

EXHIBIT L

UNITED STATES BANKRUPTCY COURT
DISTRICT OF MASSACHUSETTS
EASTERN DIVISION

In re:

NEW ENGLAND COMPOUNDING
PHARMACY, INC.,

Debtor.

Chapter 11

Case No. 12-19882-HJB

**DECLARATION OF FREDRIC L. ELLIS CONCERNING THE
NATIONAL COMPENSATION PROGRAM ESTABLISHED BY THE PROPOSED
AMENDED PLAN OF REORGANIZATION**

INTRODUCTION

1. My name is Fredric L. Ellis. I have personal knowledge of all matters set forth in this Declaration, except for those matters stated to be upon information and belief, and I believe all such matters to be true and correct. I am competent to testify under oath to the matters set forth in the Declaration if called to do so. I submit this Declaration in support of confirmation of the Joint Chapter 11 Plan of the New England Compounding Pharmacy, Inc. [Docket No. 1054] (as amended at Docket No. 1154 and thereafter from time to time, and including all exhibits and supplements thereto, the "Plan").

2. I have been an attorney in good standing in Massachusetts for over thirty years. I graduated with honors from Harvard Law School in 1983. From 1983 to 1984, I was a law clerk to Justice Raya S. Dreben of the Massachusetts Appeals Court. From 1984 to 1986, I served as an Assistant District Attorney in the Middlesex County District Attorney's Office, trying cases in the District and Superior Courts and briefing and arguing cases in the Massachusetts appellate courts, including first-degree murder cases in the Massachusetts Supreme Judicial Court. In 1986, I was appointed Deputy-Chief of the Appeals and Training Bureau for the Middlesex District Attorney's Office, supervising eleven attorneys in all aspects of appellate litigation.

3. From 1988 to 1996, I was in private practice at the Boston law firm of Gilman, McLaughlin & Hanrahan, where I was made a partner in 1991. I handled a variety of civil and criminal cases, including business litigation, products liability and class actions. In 1992, I was appointed to several plaintiffs' counsel committees in the Silicone Gel Breast Implant Product Liability Litigation, MDL-926, and was later appointed by Judge Sam Pointer of the Federal District Court in the Northern District of Alabama to serve on the MDL-926 Common Fund Disbursement Advisory Committee, which recommended appropriate attorney fee payments to attorneys for common benefit work in that litigation. The silicone gel breast implant litigation involved hundreds of thousands of claimants and over twenty defendants, was one of the largest,

if not the largest, mass torts in history with tens of thousands of individual cases filed in state and federal courts throughout the country. Several of the defendants filed for bankruptcy and there were also a number of limited fund settlements, all coordinated with the MDL proceedings. I had substantial involvement with all of these various proceedings for many years, including oversight of the claims processes established to distribute several settlement funds.

4. In 1995, I was co-counsel for plaintiffs in the trial of Toole v. Baxter Healthcare, a breast implant case in Birmingham, Alabama, which resulted in a plaintiff's verdict of \$6 million, later reduced to \$1 million on remittitur. See Toole v. Baxter Healthcare Corp., 235 F.3d 1307 (11th Cir. 2000). I was also lead trial counsel and lead appellate counsel in Mahlum v. Dow Chemical Co., in Reno, Nevada, which resulted in a \$14.15 million plaintiff's verdict in October 1995, which verdict was partially affirmed on appeal. Mahlum v. Dow Chemical Company, 114 Nev. 1468 (1998) reh'g denied, 115 Nev. 13 (1999). I was also lead trial counsel and lead appellate counsel in another breast implant case in Massachusetts, which resulted in a \$1.1 million plaintiff's verdict in 1996, which verdict was upheld on appeal. Vassallo v. Baxter Healthcare Corp., 428 Mass. 1 (1998). In May 1996, I founded the firm of Ellis & Rapacki LLP. In the late 1990s, I settled over one hundred individual breast implant cases with breast implant manufacturers. I also negotiated a settlement with the U.S. Department of Health and Human Services to resolve the government's Medicare and Medicaid reimbursement claims against breast implant manufacturers and claimants.

5. I also served as lead counsel of the Plaintiffs' Steering Committee in several bankruptcy debtor reaffirmation class actions, including In re: GECC Bankruptcy Reaffirmation Agreements Litigation, MDL-1192. I was also co-lead class counsel in Roberts v. Bausch & Lomb, in the Northern District of Alabama, a nationwide consumer class action, and Mohan v. Dell, Inc., in the San Francisco Superior Court, a California class action. I have also served as lead class counsel in numerous other class actions, including Feiss v. MediaOne Group, U.S.D.C. N.D. Ga., Ciardi v. F. Hoffmann LaRoche, Mass. Sup. Ct., Sweeney v. BASF Corp., Mass. Sup. Ct., Providence Steel v. Union Central Life Insurance Co., U.S.D.C. D. Mass., and Shabshelowitz v. Royal Maccabees Life Insurance Co., U.S.D.C. D. Mass.

6. I have also obtained numerous other jury verdicts and million dollar settlements in a wide range of other personal injury and wrongful death cases.

7. In 2005, I was appointed by Judge Denise Page Hood of the Federal District Court in the Eastern District of Michigan as Liaison Counsel for over 600 breast implant cases which opted-out of the Dow Corning Settlement Program in the Dow Corning Bankruptcy. I continue to serve in that role in coordinating the remainder of these cases in the Dow Corning Bankruptcy proceedings.

8. I have extensive experience in developing claim procedures and settlement matrixes to allocate settlement funds to claimants.

9. Since October of 2012, I have represented a number of clients with personal injury claims arising from injections of contaminated methylprednisolone acetate ("MPA") compounded by New England Compounding Pharmacy, Inc., d/b/a New England Compounding

Center (“NECC”), and I filed one of the first cases involving NECC’s products in Massachusetts state court in mid-October 2012. My clients include George Cary, individually and as the personal representative of the Estate of his wife, Lilian Cary, who died as a result of being administered contaminated MPA. Mr. Cary, who also received MPA injections, was diagnosed with fungal meningitis. Other clients of mine include those who developed fungal meningitis and other spinal fungal infections.

10. I was among the attorneys who coordinated the inspection of NECC’s premises in December 2012, and was responsible for administering the fund established by plaintiffs’ firms to conduct the inspection. I assisted in drafting the protocol for the inspection and I also coordinated the scheduling of site visits by plaintiffs’ firms from around the country.

11. In February 2012, I assisted the Creditors’ Committee’s counsel in the preliminary injunction hearing before this Court, which resulted in the issuance of injunctions, attachments and trustee process over the assets of several of NECC’s officers and directors (the “NECC Insiders”).

12. Over the last two years, I have worked closely with the Plaintiffs’ Steering Committee, and counsel for the Creditors’ Committee on a variety of issues relating to the NECC bankruptcy and the MDL proceedings. I have also consulted with numerous experts concerning the outbreak and reviewed the published scientific literature concerning the injuries caused by the outbreak.

BACKGROUND MATTERS

A. The Outbreak

13. Upon information and belief, the first suspected case of fungal meningitis was reported to the Centers for Disease Control and Prevention (“CDC”) on September 20, 2012. The CDC and later the FDA confirmed that three lots of MPA were contaminated with fungi (the “Lots”).

14. The CDC determined that, as of October 23, 2013, approximately a year after the outbreak was first detected, 64 deaths and 751 cases of fungal meningitis and fungal infections were linked to the Lots. The linked cases were classified by the CDC as follows:

State	Total Case Count	Meningitis Only	Meningitis + Paraspinal / Spinal Infection	Stroke w/out Lumbar Puncture Only	Paraspinal/ Spinal Infection only	Peripheral Joint Infection Only	Paraspinal/ Spinal Infection + Peripheral Joint Infection	Deaths
Total	751	233	151	7	325	33	2	64
FL	25	22	1	1	1	0	0	7

GA	1	1	0	0	0	0	0	0
ID	1	1	0	0	0	0	0	0
IL	2	2	0	0	0	0	0	0
IN	93	30	17	1	45	0	0	11
MD	26	23	1	0	2	0	0	3
MI	264	23	46	2	166	25	2	19
MN	12	10	0	0	2	0	0	1
NC	18	1	3	0	14	0	0	1
NH	14	9	0	0	0	5	0	0
NJ	51	30	11	0	9	1	0	0
NY	1	0	0	0	1	0	0	0
OH	20	12	3	0	5	0	0	1
PA	1	1	0	0	0	0	0	0
RI	3	1	1	0	1	0	0	0
SC	3	2	0	0	1	0	0	0
TN	153	22	57	3	69	2	0	16
TX	2	2	0	0	0	0	0	0
VA	54	41	9	0	4	0	0	5
WV	7	0	2	0	5	0	0	0

15. More information about the injuries suffered by victims of the outbreak can be found in the following published articles: Moudgal, V., et al. "Spinal and Paraspinal Fungal

Infections Associated With Contaminated Methylprednisolone Injections” *Open Forum Infectious Diseases*; 14:1(1) (May 2014); Chiller, T.M., et al. “Clinical Findings for Fungal Infections Caused by Methylprednisolone Injections” *N Engl J Med*; 369:1610-1619 (October 24, 2013); Kerker, T.M., et al. “Early Clinical Observations in Prospectively Followed Patients With Fungal Meningitis Related to Contaminated Epidural Steroid Injections” *Ann Intern Med*; 158:154-161 (February 5, 2013); and Pettit, A.C. et al. “The Index Case for the Fungal Meningitis Outbreak in the United States” *N Engl J Med*; 367:2119-2125 (November 29, 2012). To date, upon information and belief, the CDC has not linked any other NECC product to any injury or illness apart from the Lots.

B. The Tort Proofs of Claim

16. Upon information and belief, pursuant to this Court’s order, approximately 76 hospitals, clinics and doctor’s offices that injected patients with the Lots provided lists that contained the names and addresses of approximately 14,000 persons who had been injected with one of the Lots (the “Patient Lists”). Among other interested parties, those listed on the Patient Lists were sent a notice of the bar date to file proofs of claim and Personal Injury and Wrongful Death Claim Information Forms (“PITWD Addenda”) in the bankruptcy court. The bar date was January 15, 2014¹ and, upon information and belief, to date, approximately 3,500 timely tort proofs of claim and/or PITWDs have been filed.²

C. The Settlements and the Plan of Reorganization

17. In collaboration with the PSC and the Creditors Committee, and with their support, the Trustee has reached settlement agreements with NECC’s owners, insiders, affiliates, some of NEC’s outside contractors and most of their respective insurance companies. It is anticipated that these “National Settlements”³ will provide between \$130M and \$155M in cash. Under the Proposed Amended Plan of Reorganization, the vast majority of these funds will fund a Tort Trust that will distribute compensation to victims of the outbreak. Settlements totaling \$59.5M have also been reached with three healthcare providers (the “Provider Settlements”) that administered contaminated MPA to patients. The funds from the Provider Settlements will principally be distributed to Tort Claimants who were administered contaminated drugs by the three settling healthcare providers. Some portion of the Provider Settlement Funds will be available to pay administrative expenses and other unsecured claims, principally Tort Claims. One Settlement Administrator will review and make allocation determinations on the claims made to the Claims Resolution Facility for the National Settlement (the “National Settlement Administrator”), while different Settlement Administrators (the “Provider Settlement

¹ Extensions of the bar date have been granted for a group of persons who were inadvertently not mailed a notice of the bar date and for certain other persons who filed motions to extend the time to file a proof of claim.

² It is my understanding that this number represents the approximate number of tort claims filed by persons administered a NECC compound and also includes several hundred proofs of claim filed by spouses of victims alleging a loss of consortium.

³ “National Settlements” are those settlements involving defendants who, if found liable, would be liable to every victim of the outbreak.

Administrators”) will review and make allocation determinations on the claims made to the Provider Claims Resolution Facilities for the Provider Settlements.

D. The National Settlement Matrix For the Tort Trust

18. Claimants who establish that they received a contaminated NECC product may apply to the Claims Resolution Facility for one of the following seven disease or medical condition categories (the “Base Point Categories”):

BASE POINT CATEGORY	DESCRIPTION	BASE POINTS
CATEGORY I	Death After MPA Injection and (1) Spinal or Paraspinal Fungal Infection (including vertebral osteomyelitis, discitis, sacroiliitis, phlegmon, abscess and/or arachnoiditis); And/Or (2) Fungal Meningitis	55
CATEGORY II	Non-Death Fungal Meningitis and Spinal or Paraspinal Fungal Infection (including vertebral osteomyelitis, discitis, sacroiliitis, phlegmon, abscess and/or arachnoiditis) After MPA Injection	40
CATEGORY III	Non-Death Fungal Meningitis After MPA Injection	30
CATEGORY IV	Non-Death Spinal or Paraspinal Fungal Injection (including vertebral osteomyelitis, discitis, sacroiliitis, phlegmon, abscess and/or arachnoiditis) After MPA Injection	20
CATEGORY V	Peripheral Joint (e.g. hip, knee, shoulder, elbow and/or ankle) Fungal Infection After MPA Injection	10
CATEGORY VI	Symptoms of Headache, Word-Finding Difficulty, Nausea/Vomiting, Fever, Neck Stiffness or Pain, Back Pain, Photophobia, Lack of Appetite, Urine Retention, Slurred Speech, Limb Weakness, Numbness, and/or Pain at Injection Site And a Lumbar Puncture, MRI or CT Guided Biopsy After MPA Injection	1
CATEGORY VII	No Symptoms or No Lumbar Puncture, MRI or CT Guided Biopsy After MPA Injection	1/2

19. For the cases involving exposure to one or more of the Lots, the settlement matrix begins with five of the categories of conditions/illnesses defined by the CDC: 1) deaths, 2) both fungal meningitis and spinal or paraspinal fungal infection, 3) fungal meningitis, 4) spinal or paraspinal fungal infection, and 5) peripheral joint fungal infections. Two additional categories

were added: 1) one or more symptoms with lumbar puncture, MRI or CT guided biopsy and 2) no symptoms or no lumbar puncture, MRI or CT guided biopsy (a/k/a "fear cases"). With the assistance of consulting physicians who have treated hundreds of patients injured by NECC's contaminated MPA, the published literature concerning the outbreak was reviewed, and the matrix was designed in a manner which would attempt to compensate the most serious cases in each of the first six categories more than the less serious cases in each of the categories. For example, there are claimants who suffered from fungal meningitis but were not hospitalized and, after being given anti-fungal medication for 90 days, recovered. Others with fungal meningitis had extensive hospitalizations, suffered strokes and had serious complications from the anti-fungal medications. In an effort to maximize the funds that will be available to claimants from the National Settlements, a primary goal was balancing the need to compensate differently situated claimants differently, while also minimizing the administrative expenses of reviewing and approving claims. Loss of consortium and family member claims will not receive separate compensation, and a claimant may only apply for one of the seven Base Point Categories.

20. Claims for death fall into Category I. It is anticipated that the claims process (and review process) will be fairly simple for these claims. Each death case has been assigned 55 base points, with upward adjustments for age (1 point added for each year under 65, with a maximum of 20 points), number of dependent children under 18 (5 points for each, with a maximum of 15 points), for spouse (5 points), adult children (3 points for each, with a maximum of 9 points), the number of surgical debridement or irrigation surgeries (with a maximum of 8 points), anti-fungal complications (with a maximum of 28 points, if suffered all of the most serious complications), lengthy anti-fungal treatment (with a maximum of 10 points), lengthy hospitalization (1/2 point for each night hospitalized for more than 5 nights and less than 30 nights and 1/3 point for each night after 30 nights, with a maximum of 25 points), multiple lumbar punctures or CT guided biopsies (1/2 point for each more than 1, up to a maximum of 4 points), and for reduction of income (with a maximum of 9 points). The maximum number of points available for a death case is 185. The documentation required for a base death claim will vary depending on the date of death. For deaths occurring between June 2012 and September 2013, a certified death certificate that contains certain specified words or phrases (*e.g.*, meningitis, steroid injection) will constitute sufficient proof of a related death.⁴ It is anticipated that the vast majority of death claims will be able to rely on death certificates alone to establish that the death was related to the MPA injection. For those that do not, there are 2 alternative methods: 1) submission of a certified death certificate and medical documentation containing certain specified diagnoses or 2) submission of a certified death certificate and proof that the claimant was listed on a state's list of NECC death, fungal meningitis, spinal or paraspinal fungal infection or peripheral joint infection cases.⁵ For death claims where the death occurred after

⁴ The decedent's estate or representative must also establish that the decedent was injected with one of the Lots. Various methods of proof are allowed to establish this. See Claims Resolution Facility Procedures, attached as Exhibit 1, at pp. 5-6.

⁵ It is anticipated that some of these lists will be made available by the states to the Settlement Administrator pursuant to confidentiality agreements. The Michigan Attorney General's office and the Indiana Department of Health have been contacted, and both appear willing to provide their state's respective lists to the Settlement Administrator, provided that HIPAA issues are dealt with. Similar requests have been made to the Department of Public Health and/or the AG's offices in Tennessee and Virginia, and they appear to be willing to provide the lists if

September 30, 2013, proof that the death was related to one of the Lots or complication arising therefrom must be submitted by the Claimant and deemed sufficient by the Settlement Administrator.⁶

21. As with establishing that a death was related to the MPA injection or complication arising therefrom, the matrix sets forth other presumptions for the Settlement Administrator in order to simplify the review process when the claimant has documented that he or she was injected with one of the Lots. Certain questions will be asked of the claimant on the compensation claim form to ensure that these presumptions are appropriate for a particular claim.

22. The non-death claims involving fungal meningitis and/or spinal or paraspinal fungal infection (CATEGORIES II-IV) have various base point values ranging from 20-40 with a variety of upward adjustments for aggravating circumstances. As with the death cases, this provides a method to cover the range from mild cases to extremely serious cases in each of the Base Point Categories. For example, our consulting physicians advised us that a fungal infection of the sacroiliac joint (the joint at the bottom of the spine) is more serious and painful than other areas of the spine and that arachnoiditis and vertebral osteomyelitis are more serious than other types of spinal/paraspinal infections. Similarly, for the peripheral joint infection category (CATEGORY V) with a base point value of 10, we were advised that an infection of a hip is more serious than an infection of an ankle or knee joint. Many of the upward adjustments available in these categories (i.e. Lengthy Hospitalization Adjustment, Surgical Debridement and/or Irrigation Surgery Adjustment, Anti-Fungal Complication Adjustment, Length of Anti-Fungal Treatment Adjustment, Stoke Adjustment, Multiple Lumbar Punctures or CT Guided Biopsies Adjustment, Income Adjustment) are the same as the adjustments available for death cases, and all are attempts to provide more compensation for the more serious cases in a particular category. The final two categories, CATEGORY VI, (involving one or more symptoms and either a lumbar puncture, MRI or CT guided biopsy), and CATEGORY VII, ("fear cases"), are expected to have the largest number of claims.⁷

23. It should be noted that the upper end of the point value ranges for the fungal meningitis and spinal/paraspinal infection categories will likely never be reached in any category because the very serious complications from anti-fungal treatment required for some of the Anti-Fungal Complication Adjustments are rare (permanent dialysis, liver transplant), and it is extremely unlikely that one claimant would experience all of them and be entitled to receive the full amount of the Anti-Fungal Complication Adjustments.

certain conditions are met. If these states agree to provide their lists, I believe that many of the remainder of the affected states will also provide lists.

⁶ The CDC stopped updating its death list after no deaths were reported between September 6, 2013 and October 23, 2013. In view of the ages of most claimants (the median age of those who were diagnosed with fungal meningitis or a spinal or paraspinal fungal infection is approximately 64), some of this population had comorbidities, and a death occurring over a year after the outbreak may be unrelated. If it is related, the claimant will need to establish that to the satisfaction of the Settlement Administrator. While this individual proof will increase administrative expenses to some extent, it is anticipated that the number of claims involving deaths after September 30, 2013 will be minimal.

⁷ It is estimated that there may be 500 – 1,000 claims filed under each of these two categories.

24. Two other types of claims, those involving other NECC products (other than the Lots) and those involving bacterial infection or bacterial meningitis are dealt with slightly differently than those involving the Lots and fungal meningitis or fungal infections for a number of reasons: 1) upon information and belief, the CDC has not linked any NECC product that was compounded in 2012 other than the Lots to any injury or illness; 2) the CDC tested numerous compounds from NECC and found only 9 non-MPA lots to be contaminated; 3) the CDC has not linked any case of bacterial infection or bacterial meningitis to any NECC product that was compounded in 2012, including the Lots; and 4) as opposed to fungal meningitis and fungal infections, bacterial infections are quite common (as just an example, upon information and belief, there are over 500,000 cases of staph infections annually in the U.S). As a result, the settlement matrix provides that, for claims involving NECC products other than the Lots, the claimant must establish that the lot of NECC product administered to the claimant was contaminated, *i.e.* one of the 9 lots of non-MPA found to be contaminated after the CDC tested numerous lots of compounds from NECC.⁸ For all claims involving alleged bacterial contamination, the claimant must establish that the specific bacteria that caused the bacterial infection or bacterial meningitis in the claimant was present in the lot of the NECC product administered to the claimant.

E. The Process of Developing the Settlement Matrix

25. As noted above, the settlement matrix was largely based upon the categories of illnesses developed by the CDC. During the spring of 2014, consulting physicians were retained by the Plaintiffs' Steering Committee who assisted with the drafting and revising of the matrix. In July 2014, a draft of the matrix was distributed to all known plaintiffs' counsel who represent victims of the outbreak and many of these counsel provided further input concerning the point values to be awarded for certain conditions and for certain Upward Adjustments. The matrix was tested by taking over 100 cases from different parts of the country (including cases of certain PSC members and cases of non-PSC members) and calculating the awards that would be given in those cases. All involved in this testing process believed that the matrix was able to capture the wide range of injuries suffered by the victims in a fair and equitable manner.

F. Distribution of Compensation Claim Packages and the Compensation Claims Deadline

26. Within fourteen (14) days of the "Effective Date"⁹, the National Settlement Administrator shall mail, via first class mail, a NECC Victims Compensation Program Claim Form ("Compensation Claim Form"), together with Instructions, a Base Point Category and Adjustment Worksheet, a W-9 Form, and a set of FAQs to those persons who filed a timely tort

⁸ It is estimated that there will be approximately 25-50 "other product" claims and that the majority will involve bacterial infections.

⁹ The Effective Date is defined in the Amended Plan as the first business day after 14 days after the confirmation order is entered by the Bankruptcy Court, provided that no stay of the confirmation order has been entered by a Court before that day.

Proof of Claim or PITWD Addendum in the NECC bankruptcy. The claims deadline will be one hundred and twenty (120) days after the Effective Date.

G. Establishment of a Claims Assistance Program

27. The National Settlement Administrator will develop, staff and maintain a program for providing claims assistance to Claimants and their attorneys. The program will be part of the Claims Resolution Facility and staffed by employees of the Facility who have been trained to offer assistance regarding the Claims Resolution Facility Procedures, eligibility requirements, submission requirements (including the documentation required), provisional denials, the processes for curing deficiencies, obtaining re-reviews for error, and requesting reconsideration under a different Base Point Category, as well as the appeal procedure in the event of a Final Denial of a claim. The Claims Assistance Program staff will also be responsible for responding to inquiries concerning the status of a Claimant's claim. The Claims Assistance Program staff shall not provide legal or tax advice to Claimants.

H. Initial Review of Claims

28. As soon as possible after the Claims Deadline, the National Settlement Administrator shall conduct an initial review of all Compensation Claim Forms to determine if each Claimant filed a timely Proof of Claim or PITWD Addendum in NECC's bankruptcy. If no timely Proof of Claim or PITWD Addendum was filed by a Claimant, the Settlement Administrator shall make a final determination denying the Claimant's claim and shall notify the Claimant of the denial, as well as inform the Claimant of the procedure to appeal to the Appeals Administrator. All claims not denied after this process is completed will be deemed to be Eligible Claims.

29. The National Settlement Administrator shall then calculate the total amount of points claimed (as stated on the Compensation Claim Form) for all Eligible Claims (the "Summed Points") and compute a tentative dollar value for each Claimed Point ("Tentative Point Value") according to the following formula: (i) multiply the Summed Points by a factor of 1.5 (the "Enhanced Points") and (ii) divide the National Fund Net Proceeds (the amount available to be distributed to Claimants at the time the calculation is made, which amount will be supplied to the Settlement Administrator by the Tort Trustee) by the number of Enhanced Points.

I. Processing Claims

30. The National Settlement Administrator shall then review the Eligible Claims in the order in which they were received, using the criteria as set forth in pages 5 through 40 of the Claims Resolution Facility Procedures (attached as Exhibit A to the Tort Trust Agreement [Docket No. 1123-1]).

31. If an eligible claim is allowed in full, the National Settlement Administrator shall send a Notice of Final Determination to each such Claimant that informs them of 1) the allowance of the claim in full, 2) that the Initial Payment constitutes interim compensation, and 3) that the Claimant may receive additional compensation after the Claims Process is completed and all appeals from the National Settlement Administrator's final determinations have been

resolved. If the National Settlement Administrator has received a completed W-9 form from the Claimant, the National Settlement Administrator shall notify the Tort Trustee of the Allowed Claim, and that payment shall be made to the Claimant in an amount equivalent to the Claimant's Approved Points multiplied by the Tentative Point Value (the "Initial Claim Value").

32. If an Eligible Claim is not approved in full by the Settlement Administrator, it shall be deemed to be provisionally denied ("Provisional Denials"). Provisional Denials shall consist of Eligible Claims denied in whole (e.g. claims did not meet the proof requirements for the Base Point Category applied for) or denied in part (e.g. one or more adjustments applied for was not awarded). For each Eligible Claim denied in part, the Settlement Administrator shall sum the points that have been approved for that claim ("Approved Points") and determine the Initial Claim Value of the claim as approved according to the formula: Approved Points x Tentative Point Value = Initial Claim Value.

33. For each Provisional Denial, the National Settlement Administrator shall notify the Claimant of the Provisional Denial and the specific reason(s) for the Provisional Denial. For claims denied in part, the National Settlement Administrator shall notify the Claimant of the number of Approved Points and the Initial Claim Value for the claim. All Notices of Provisional Denials shall also inform the Claimant of (1) the procedures and deadlines for correcting deficiencies, obtaining a re-review for error, or obtaining reconsideration under a different Base Point Category, and (2) the availability of assistance through the Claims Assistance Program.

J. Reviews and Appeals of Claim Denials

34. The Claims Resolution Facility Procedures provide for a multi-level review of claims submitted by tort claimants. If a claim is provisionally denied, in whole or in part, the claimant is provided an opportunity to cure any deficiency in the claim identified by the National Settlement Administrator, to request reconsideration of the claim by the National Settlement Administrator, or request that the claim be considered under a different Base Point Category than the original claim. If the claim is then finally denied, in whole or in part, by the National Settlement Administrator, the claimant is given the right to appeal the final denial to the Appeals Administrator. The Appeals Administrator will then conduct a *de novo* review of the denial. Determinations of the Appeals Administrator are final and binding.

K. Final Payments to Tort Claimants

35. The Claims Resolution Facility Procedures provide that, within 120 days after all claims are finally determined, all appeals are resolved by the Appeals Administrator, and the final resolution of any appeal of this Court's confirmation order, the National Settlement Administrator shall compute the final dollar value of each Approved Point (the "Final Point Value"). If the Final Point Value is greater than the Tentative Point Value (which was used to calculate the Initial Payments) then each Tort Trust Beneficiary will receive a payment in the amount of the Final Point Value multiplied by the amount of points awarded the Tort Trust Beneficiary, minus the amount of any Initial Payment previously received.

L. Prevention and Detection of Fraud

36. The National Settlement Administrator will implement procedures and conduct audits to detect and prevent the allowance of fraudulent claims. All Compensation Claim Forms must be signed under the pains and penalties of perjury, and the submission of a fraudulent claim may subject those responsible to criminal prosecution.

M. Final Report of the National Settlement Administrator and Closure of the Claims Resolution Facility

37. Pursuant to the Claims Resolution Facility Procedures, within ninety (90) days after all Qualified Claims have been paid by the Tort Trust, the National Settlement Administrator shall wind up the affairs of the Claims Resolution Facility, and the Tort Trustee and National Settlement Administrator shall file a joint report with this Court and the District Court. The final report shall specify the total number of claims filed in each of the seven Base Point Categories, the Tentative Point Value determined for each point, the Final Point Value for each point, the total number of Qualified Claims in each Base Point Category, the total number of points awarded in each Base Point Category, and the total amounts paid to each Tort Trust Beneficiary in each Base Point Category.

**THE COMPENSATION PROGRAM'S
ALLOCATION PROCESS IS FAIR AND REASONABLE**

38. I believe that the Claims Resolution Facility Procedures set forth a fair and equitable process for determining how the total settlement amount available for distribution from the National Settlements will be allocated. The allocation is based on objective factors and is overseen by neutrals. All claimants will have the opportunity to submit information concerning their individual cases to a neutral – the National Settlement Administrator – and have an opportunity to appeal any full or partial final denial of their claim to another neutral – the Appeals Administrator.

39. I also believe that the matrix set forth in the Claims Resolution Facility Procedures strikes the appropriate balance between keeping the criteria simple, which minimizes the costs of administering the settlement, and recognizing that the victims have suffered a wide range of injuries. Even within the Base Point Categories themselves, there are a range of injuries. In sum, I believe that the settlement matrix appropriately weighs a variety of factors to allocate the National Settlement Funds to victims in a fair, reasonable and equitable manner without incurring unreasonable administrative expenses and delay.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Dated: April 27, 2015

By: 
Fredric L. Ellis

EXHIBIT 1

Case 12-19882 Doc 1123-2 Filed 02/13/15 Entered 02/13/15 17:03:04 Desc
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EXHIBIT A TO TORT TRUST AGREEMENT:
CLAIMS RESOLUTION FACILITY PROCEDURES

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INTRODUCTION AND GENERAL PROVISIONS

A PERSONAL INJURY AND WRONGFUL DEATH CLAIMS RESOLUTION

FACILITY (the "Claims Resolution Facility") is hereby established in accordance with the Joint Chapter 11 Plan of New England Compounding Pharmacy, Inc. (the "Plan") and the Tort Trust Agreement (the "Tort Trust Agreement"), the latter of which establishes the Tort Trust (the "Tort Trust").¹

A. Among its provisions, the Plan provides for the resolution, disposition and satisfaction of the Tort Claims, as defined and identified therein, all of which Claims arise out of personal injury or death, in accordance with the Tort Trust Agreement and this Claims Resolution Facility.

B. The Tort Trust Agreement establishes the Tort Trust, the principal purpose of which is to satisfy the Tort Claims.

C. The purposes of the Claims Resolution Facility are (1) to evaluate each of the Tort Claims according to the procedures established herein, with the least practicable cost to the Trust, (2) to determine for each Allowed Tort Claim a fair and equitable compensation amount to be distributed from the Tort Trust, and (3) to effectuate such distributions as expeditiously as possible.

D. To facilitate, effectuate and implement the purposes of the Claims Resolution Facility, Epiq Class Action and Claim Solutions, Inc. (the "National Settlement Administrator") is hereby retained and appointed to execute the functions described herein in accordance with the terms of the Trust Agreement. The National Settlement Administrator shall oversee all aspects

¹ Unless the context otherwise requires, all capitalized terms used in these Claims Resolution Facility Procedures and not otherwise defined herein shall have the meanings assigned to them in the Plan and/or the Tort Trust Agreement.

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of the Claims Resolution Facility and shall prepare and distribute to the Tort Trustee periodic reports documenting the activities of the Claims Resolution Facility, including reports on Tort Claim submissions and resolution. In the event that the National Settlement Administrator resigns or is removed from office or is otherwise unable to perform the functions of the National Settlement Administrator, a successor National Settlement Administrator shall be appointed by the District Court, as defined in the Tort Trust Agreement, after notice and opportunity to be heard by persons having Tort Claims. The National Settlement Administrator shall receive reasonable compensation in an amount consistent with that of similar functionaries in similar types of proceedings and shall be reimbursed by the Tort Trust for his or her reasonable expenses, including travel expenses, reasonably required and incurred in the performance of his or her duties in accordance with the provisions of the Tort Trust Agreement and the provisions of any retention agreement between the Tort Trustee and the National Settlement Administrator. The National Settlement Administrator may employ staff as he/she deems necessary to assist him/her in the performance of his/her duties and the expenses of doing so shall be paid by the Tort Trust in accordance with the provisions of the Tort Trust Agreement and the provisions of any retention agreement between the Tort Trustee and the National Settlement Administrator. The National Settlement Administrator may also consult with the Trust Advisory Board in accordance with the provisions of the Tort Trust Agreement. The National Settlement Administrator may also retain consultants in accordance with the provisions of the Tort Trust Agreement and with the provisions of any retention agreement between the Tort Trustee and the National Settlement Administrator.

E. To provide for an appeal process from Claim denials, upon entry of an order by the District Court pursuant to 28 U.S.C. § 636, Magistrate Judge Kenneth P. Neiman will be

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appointed as Appeals Administrator. If no such order is entered by the District Court within 30 days of the Plan Effective Date, then Kenneth Feinberg, Esq. will be deemed to be appointed as Appeals Administrator. In the event the Appeals Administrator resigns or is removed from office or is otherwise unable to perform the functions of the Appeals Administrator, the District Court shall appoint a successor Appeals Administrator.

F. When notice is required to be sent to a Tort Trust Beneficiary pursuant to these procedures, if the Tort Trust Beneficiary is represented by an attorney as indicated on the Tort Trust Beneficiary's NECC National Compensation Claim Form ("National Compensation Claim Form"), notice shall be provided to both the Tort Trust Beneficiary and the attorney at the addresses listed on the Tort Trust Beneficiary's National Compensation Claim Form, unless updated by the Tort Trust Beneficiary or attorney. Distributions to Tort Trust Beneficiaries who are represented by attorneys shall be made jointly to the Tort Trust Beneficiary and the attorney (or law firm). If a Tort Trust Beneficiary is not represented by an attorney, distributions shall be made payable to the Tort Trust Beneficiary.

G. It shall be the responsibility of the Tort Trust Beneficiary and/or his or her attorney to notify the National Settlement Administrator of address changes of the Tort Trust Beneficiary or the attorney and any other changes with respect to the information provided by the Tort Trust Beneficiary on a completed W-9 form.

H. To the extent that any of these Claims Resolution Facility Procedures conflicts with any provision of the Confirmation Order, the Plan, or the Tort Trust Agreement, the conflicting provision of the Confirmation Order, the Plan, or the Tort Trust Agreement, in that descending order of precedence, shall control.

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PROCEDURES OF THE CLAIMS RESOLUTION FACILITY

Pursuant to the Plan and the Tort Trust Agreement, the Tort Trustee shall make distributions as per the terms of the Tort Trust Agreement and these Claims Resolution Facility Procedures. Under the Plan, Confirmation Order, Tort Trust Agreement and these Claims Resolution Facility Procedures, each Tort Trust Beneficiary whose Tort Claim is allowed shall receive his or her individually allocated distribution of the National Fund Net Trust Proceeds. Allocations shall be determined by the National Settlement Administrator, based upon the factors, methodologies and procedures set forth herein.

I. Distribution of NECC National Compensation Program Claim Forms

Within 14 days of the Effective Date, the National Settlement Administrator shall mail a National Compensation Program Claim Form, together with instructions, a Base Point Category and Adjustment Calculation Worksheet, a set of Frequently Asked Questions, and a W-9 Form to the Tort Trust Beneficiaries identified by the Tort Trustee who filed, or who had filed on their behalf, a timely Proof of Claim or Personal Injury and Wrongful Death Claim Information Form ("PITWD Addendum") in the Chapter 11 Case.

II. Procedures for Filing National Compensation Claim Forms

A. To receive compensation from the Qualified Settlement Fund, Tort Trust Beneficiaries must submit a completed and signed National Compensation Claim Form to the National Settlement Administrator, together with all supporting documentation required, on or before [insert date 120 days after Effective Date], 2015, at 5:00 P.M., Eastern Standard Time. All National Compensation Claim Forms must be received by the National Settlement Administrator by this date and time. No National Compensation Claim Forms may be accepted by the National Settlement Administrator between this date and the date the National Settlement Administrator calculates the Tentative Point Value pursuant to Section VIII.A below, except

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upon a showing of excusable neglect as determined by the National Settlement Administrator or, on appeal, to the Appeals Administrator. No National Compensation Claim Forms shall be accepted by the National Settlement Administrator after the date the National Settlement Administrator has calculated the Tentative Point Value pursuant to Section VIII.A herein, except those submitted as Resubmitted Claims pursuant to Section X.A herein. The National Settlement Administrator may also accept as timely National Compensation Claim Forms that are submitted in error (but which are otherwise timely) to the Bankruptcy Court, the District Court, or Donlin Recano.

B. The filing of a National Compensation Claim Form also constitutes participation by that Tort Trust Beneficiary's family members in the primary Tort Trust Beneficiary's Claim or the Class D Estate Claim and Class D Consortium Claims of family members shall be deemed released by the treatment afforded the primary Tort Trust Beneficiary under and in accordance with these Claims Resolution Facility Procedures.

III. Determination of Eligible Claims Based on Previously Submitted Proofs of Claims or PITWD Addenda in the NECC Bankruptcy Case and a Completed W-9 Form

A. In order to be eligible to receive compensation from the Tort Trust, a Tort Trust Beneficiary must have previously filed in the Chapter 11 Case a timely Proof of Claim or PITWD Addendum, or had a timely Proof of Claim or PITWD Addendum filed on his or her behalf (the Proof of Claim and PITWD Addenda so filed, collectively, "Timely Proofs of Claim or PITWD Addenda"). Proofs of Claim or PITWD Addenda that were allowed by the Bankruptcy Court to be filed after the Bar Date will be deemed to be Timely Proofs of Claim and PITWD Addenda.

B. The National Settlement Administrator shall conduct an initial review of all National Compensation Claim Forms and the Timely Proofs of Claim and PITWD Addenda filed

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by or on behalf of each Tort Trust Beneficiary. If no Timely Proof of Claim or PITWD Addendum was filed by or on behalf of a given Tort Trust Beneficiary, the National Settlement Administrator shall make a final determination denying that Tort Trust Beneficiary's Tort Claim and shall notify the Tort Trust Beneficiary of such final denial and the procedure to appeal to the Appeals Administrator. Notwithstanding anything contained herein to the contrary, a Tort Trust Beneficiary receiving such a final denial may file an appeal with the Appeals Administrator in accordance with the provisions of Section XI below.

C. While conducting the initial review described in Section III.B., herein, the National Settlement Administrator shall also determine if the Tort Trust Beneficiary submitted a completed W-9 form with his or her National Compensation Claim Form. If a completed W-9 form was not submitted by a Tort Trust Beneficiary, the National Settlement Administrator shall notify the Tort Trust Beneficiary that one must be submitted within 90 days of such notice or the claim will be finally denied. In the event of such a final denial, the National Settlement Administrator shall notify the Tort Trust Beneficiary of the final denial and the procedure to appeal to the Appeals Administrator. Notwithstanding anything contained herein to the contrary, a Tort Trust Beneficiary receiving such a final denial may file an appeal with the Appeals Administrator in accordance with the provisions of Section XI herein.

D. All Tort Claims not denied for lack of a Timely Proof of Claim, PITWD Addendum or lack of a completed W-9 form shall be deemed to be "Eligible Claims" and persons holding such Eligible Claims shall be deemed "Eligible Tort Trust Beneficiaries."

IV. Eligible Claims Involving Injections From One or More of the Three Contaminated MPA Lots

A. Proof of Exposure to One or More of the Three Contaminated MPA Lots

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In order for an Eligible Claim to qualify for any of the seven Base Point Categories described in Section IV.B herein (and thus to be deemed a "Qualified Claim"), the Eligible Tort Trust Beneficiary must submit to the National Settlement Administrator medical or other records documenting that the Tort Trust Beneficiary received an injection or injections from one or more of lots 05212012@68, 06292012@26 or 08102012@51 (the "Three Contaminated MPA Lots") of preservative-free methylprednisolone acetate ("MPA") compounded by New England Compounding Pharmacy ("NECC"), *i.e.* a letter from pain clinic, hospital or doctor's office informing the Tort Trust Beneficiary that he/she had received an injection from one of the Three Contaminated MPA Lots. Alternatively, if the Eligible Tort Trust Beneficiary (on the National Compensation Claim Form) has requested that the National Settlement Administrator review the lists of patients who received an injection from one of the Three Contaminated MPA Lots that clinics, hospitals and doctor's offices submitted to the Chapter 11 Trustee pursuant to the *Interim Order Regarding Chapter 11 Trustee's Motion for an Order Establishing Bar Dates for Filing Proofs of Claim and for Related Relief Concerning Notice by Notice Intermediaries* [Bankr. Dkt. No. 412] (the "Patient Lists"), and the states' lists of NECC death, stroke, fungal meningitis, spinal or paraspinal infection and/or peripheral joint infection cases (the "State NECC Lists"), and if these lists are available to the National Settlement Administrator, the National Settlement Administrator shall review the relevant Patient List(s) and State NECC lists in order to determine if the Tort Trust Beneficiary's name is on one of such lists. If the Tort Trust Beneficiary's name was listed on any such list, this will provide the necessary proof of injection from one of the Three Contaminated MPA Lots.

B. The Seven Base Point Categories

Eligible Tort Trust Beneficiaries who establish that they received an injection or injections from one or more of the Three Contaminated MPA Lots may apply for one of the following seven disease or medical condition categories ("Base Point Categories"):

1. Death After MPA Injection and (1) Spinal or Paraspinal Fungal Infection (including vertebral osteomyelitis, discitis, sacroiliitis, epidural or paraspinal phlegmon, epidural or paraspinal abscess and/or arachnoiditis) And/Or (2) Fungal Meningitis ("CATEGORY I");
2. Non-Death Fungal Meningitis and Spinal or Paraspinal Fungal Infection (including vertebral osteomyelitis, discitis, sacroiliitis, epidural or paraspinal phlegmon, epidural or paraspinal abscess and/or arachnoiditis) After MPA Injection ("CATEGORY II");
3. Non-Death Fungal Meningitis After MPA Injection ("CATEGORY III");
4. Non-Death Spinal or Paraspinal Fungal Infection (including vertebral osteomyelitis, discitis, sacroiliitis, epidural or paraspinal phlegmon, epidural or paraspinal abscess and/or arachnoiditis) After MPA Injection ("CATEGORY IV");
5. Peripheral Joint (e.g. hip, knee, shoulder, elbow or ankle) Fungal Infection After MPA Injection ("CATEGORY V");
6. Headache, Word-Finding Difficulty, Nausea/Vomiting, Fever, Neck Stiffness or Pain, Back Pain, Photophobia, Lack of Appetite, Urine Retention, Slurred Speech, Limb Weakness, Numbness, and/or Pain at Injection Site And a Lumbar Puncture, MRI or CT Guided Biopsy After MPA Injection ("CATEGORY VI");
7. No Symptoms or No Lumbar Puncture, MRI or CT Guided Biopsy After MPA Injection ("CATEGORY VII").

C. Additional Proof Required for CATEGORY I Claims

In order for a Qualified Claim made for CATEGORY I to be allowed, the Eligible Tort Trust Beneficiary must also submit to the National Settlement Administrator (1) a certified death certificate documenting that the death occurred after injection from one of the Three

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Contaminated MPA Lots and with the immediate or underlying cause of death containing one of the following words or phrases: "meningitis," "meningoencephalitis," "encephalitis," "epidural injection," "methylprednisolone injection," "steroid injection," "exserehilum," "aspergillus," "abscess," or "arachnoiditis;" or (2) a certified death certificate and medical documentation of (a) a diagnosis of fungal meningitis, meningoencephalitis, or encephalitis or documentation of headache, fever, stiff neck and/or photophobia and CSF profile showing pleocytosis (>5 white blood cells, adjusting for presence of red blood cells by subtracting 1 white blood cell for every 500 red blood cells present, regardless of glucose or protein levels) after injection from one of the Three Contaminated MPA Lots; and (b) documentation that the Tort Trust Beneficiary received anti-fungal treatment; or (3)(a) a certified death certificate and medical documentation of a diagnosis of spinal or paraspinal fungal infection, including vertebral osteomyelitis, discitis, sacroiliitis, epidural or paraspinal phlegmon, epidural or paraspinal abscess, or arachnoiditis (or, for arachnoiditis, documentation of intradural clumping, abnormal thickening or unevenness of nerve roots after MRI), after spinal or paraspinal injection from one of the Three Contaminated MPA Lots (including, but not limited to, spinal facet joint injection, sacroiliac joint injection or spinal or paraspinal nerve root/ganglion block injection); and (b) documentation that the Tort Trust Beneficiary received anti-fungal treatment; or (4) a certified death certificate and medical documentation of a cerebrovascular accident/stroke (but not a transient ischemic attack only) occurring after injection from one of the Three Contaminated MPA Lots and on or before December 31, 2012; or (5) a certified death certificate and proof that the Tort Trust Beneficiary was listed on the State NECC Lists of death cases. If such proof is presented, for deaths occurring before September 30, 2013, the National Settlement Administrator shall presume that the death was the result of the MPA injection or complication(s) arising therefrom unless there is

cause to believe that the death was the result of an unrelated event (*i.e.*, auto accident, unrelated illness). For deaths occurring after September 30, 2013 and for deaths where there is a reason to believe that the death resulted from an unrelated event, a certified death certificate and such other proof deemed sufficient by the National Settlement Administrator to establish that the death was the result of the MPA injection or complication(s) arising therefrom is required. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.* the Tort Trust Beneficiary's medical records only state that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary. This presumption, as used throughout these Procedures, shall only apply for the purposes of evaluating Tort Claims under these Procedures. This presumption does not affect the calculation of the statute of limitations, statute of repose, or any other time calculation for any other purpose and does not constitute an admission or waiver of any legal position by Tort Trust Beneficiaries. If these requirements are met, the National Settlement Administrator shall award 55 base points to the Tort Trust Beneficiary.

D. Additional Proof Required for CATEGORY II Claims

In order for a Qualified Claim made for CATEGORY II to be allowed, the Eligible Tort Trust Beneficiary must also submit to the National Settlement Administrator (I)(a) medical documentation of a diagnosis of fungal meningitis, meningoencephalitis and/or encephalitis or documentation of headache, fever, stiff neck and/or photophobia and CSF profile showing

pleocytosis (>5 white blood cells, adjusting for presence of red blood cells by subtracting 1 white blood cell for every 500 red blood cells present, regardless of glucose or protein levels) after injection from one of the Three Contaminated MPA Lots, and (b) medical documentation of a diagnosis of spinal or paraspinal fungal infection, including vertebral osteomyelitis, discitis, sacroiliitis, epidural or paraspinal phlegmon, epidural or paraspinal abscess, or arachnoiditis (or, for arachnoiditis, documentation of intradural clumping, abnormal thickening or unevenness of nerve roots after MRI), after spinal or paraspinal injection from one of the Three Contaminated MPA Lots (including, but not limited to, spinal facet joint injection, sacroiliac joint injection or spinal or paraspinal nerve root/ganglion block injection); and (c) documentation that the Tort Trust Beneficiary received anti-fungal treatment, or (2) proof that the Tort Trust Beneficiary was listed on the State NECC Lists of fungal meningitis or stroke cases, and was listed on the State NECC Lists of spinal or paraspinal fungal infection cases or was listed on a state list of NECC fungal meningitis and spinal or paraspinal infection cases. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary. If such requirements are met, the National Settlement Administrator shall award 40 base points to the Tort Trust Beneficiary.

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E. Additional Proof Required for CATEGORY III Claims

In order for a Qualified Claim made for CATEGORY III to be allowed, the Eligible Tort Trust Beneficiary must also submit to the National Settlement Administrator (1)(a) medical documentation of a diagnosis of fungal meningitis, meningoencephalitis and/or encephalitis or documentation of headache, fever, stiff neck and/or photophobia and CSF profile showing pleocytosis (>5 white blood cells, adjusting for presence of red blood cells by subtracting 1 white blood cell for every 500 red blood cells present, regardless of glucose or protein levels) after injection from one of the Three Contaminated MPA Lots and (b) documentation that the Tort Trust Beneficiary received anti-fungal treatment; or (2) proof that the Tort Trust Beneficiary was listed on the State NECC Lists of fungal meningitis or stroke cases. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary. If such requirements are met, the National Settlement Administrator shall award 30 base points to the Tort Trust Beneficiary.

F. Additional Proof Required for CATEGORY IV Claims

In order for a Qualified Claim made for CATEGORY IV to be allowed, the Eligible Tort Trust Beneficiary must also submit to the National Settlement Administrator (1)(a) medical documentation of a diagnosis of spinal or paraspinal fungal infection, including vertebral

osteomyelitis, discitis, sacroiliitis, epidural or paraspinal phlegmon, epidural or paraspinal abscess, or arachnoiditis (or, for arachnoiditis, documentation of intradural clumping, abnormal thickening or unevenness of nerve roots after MRI), after spinal or paraspinal injection from one of the Three Contaminated MPA Lots (including, but not limited to, spinal facet joint injection, sacroiliac joint injection or spinal or paraspinal nerve root/ganglion block), and (b) documentation that the Tort Trust Beneficiary received anti-fungal treatment; or (2) proof that the Tort Trust Beneficiary was listed on the State NECC Lists of spinal or paraspinal fungal infection cases. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary. If such requirements are met, the National Settlement Administrator shall award 20 base points to the Tort Trust Beneficiary.

G. Additional Proof Required for CATEGORY V Claims

In order for a Qualified Claim made for CATEGORY V to be allowed, the Eligible Tort Trust Beneficiary must also submit to the National Settlement Administrator medical documentation of (1)(a) a diagnosis of peripheral joint (e.g. hip, knee, shoulder, elbow or ankle) fungal infection (including, but not limited to, osteomyelitis and septic arthritis) after injection from one of the Three Contaminated MPA Lots into the osteoarticular structure of a peripheral

joint (including the bursa and peripheral nerve complex) and (b) that the Tort Trust Beneficiary received anti-fungal treatment; or (2) proof that the Tort Trust Beneficiary was listed on the State NECC Lists of peripheral joint fungal infection cases. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary. If such requirements are met, the National Settlement Administrator shall award 10 base points to the Tort Trust Beneficiary.

H. Additional Proof Required for CATEGORY VI Claims

In order for a Qualified Claim made for CATEGORY VI to be allowed, the Eligible Tort Trust Beneficiary must also submit to the National Settlement Administrator (1) contemporaneous medical records documenting that the Tort Trust Beneficiary suffered from one or more of the following symptoms: headache, word-finding difficulty, nausea/vomiting, fever, neck stiffness or pain, back pain, photophobia, lack of appetite, urine retention, slurred speech, limb weakness, numbness, and/or pain at injection site after injection from one of the Three Contaminated MPA Lots and before March 31, 2013 and (2) medical records documenting one lumbar puncture, MRI or CT guided biopsy after injection from one of the Three Contaminated MPA Lots and prior to April 30, 2013. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of

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injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the Patient List(s)), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary. If such requirements are met, the National Settlement Administrator shall award 1 base point to the Tort Trust Beneficiary.

I. Additional Proof Required for CATEGORY VII Claims

There is no additional proof required for CATEGORY VII claims. All Qualified Claims for CATEGORY VII shall be allowed by the National Settlement Administrator and be awarded $\frac{1}{2}$ base point.

J. Upward Adjustments to Qualified Claims

1. *Age Adjustment as of Date of Death for CATEGORY I*

For Qualified Claims awarded 55 base points under CATEGORY I, the National Settlement Administrator shall also award an additional point for each year decedent's age was less than 65 on the date of death, up to a maximum of 20 points, as evidenced by the decedent's certified death certificate.

2. *Adjustment for Dependent Children Under 18 for CATEGORY I*

For Qualified Claims awarded 55 base points under CATEGORY I, the National Settlement Administrator shall also award an additional 5 points for each dependent child under the age of 18 that the decedent had as the date of death, up to a maximum of 15 points.

- (a) For this Dependent Children Adjustment, a child is considered to have been dependent on the decedent if he or she was
- (i) Under the age of 18 as of the date of death and listed as a qualifying dependent child on the decedent's 2011 or 2012 federal income tax return; or
 - (ii) A natural or legitimate child under the age of 18 as of the date of death; or
 - (iii) An adopted child under the age of 18 as of the date of death; or
 - (iv) A stepchild under the age of 18 as of the date of death, who lived with the decedent in a regular parent-child relationship at the time of the decedent's death or did not live with the decedent because of medical reasons or to attend school or for other similar reasons; or
 - (v) Under the age of 18 as of the date of death who lived with the decedent in a regular parent-child relationship at the time of the decedent's death or did not live with the decedent because of medical reasons, to attend school or other similar reasons, and to whose support the decedent made regular and substantial contributions.
- (b) Proof that a child was under 18 as of the date of death may be provided by submitting the decedent's 2011 or 2012 federal tax return, listing the child as a dependent and listing the child's date of birth or a certified birth certificate of the child.
- (c) Proof that a child was a dependent may be provided by submitting:
- (i) a copy of the decedent's 2011 or 2012 federal tax return, listing the child as a qualifying dependent child; or
 - (ii) a certified birth certificate that indicates that a child was a natural or legitimate child of the decedent. In the event that decedent's name does not appear on the birth certificate, proof may be provided by documentation evidencing a judicial determination of support; or
 - (iii) for domestic adoptions, a copy of a revised birth certificate showing the decedent as a parent. For foreign adoptions, proof may be provided by submitting a copy of the adoption decree and, if applicable, documentation showing the child's change of name. Since rules for foreign adoptions vary by country, alternative and/or additional documentation may be required by the National Settlement Administrator; or
 - (iv) for a child that is a stepchild, a certificate of marriage evidencing the marriage of the child's biological parent and the decedent, and a certified birth certificate or documentation evidencing a judicial determination of support and a statement from a person with direct knowledge that verifies that the stepchild (or stepchildren) lived with the decedent in a regular parent-child relationship at the time of the

- decedent's death or describing the reasons why the stepchild did not live with the decedent (such as for medical reasons, to attend school, or for other similar reasons); or
- (v) if dependency is claimed on the basis of the decedent having made regular and substantial contributions to the support of the child, a signed statement from a person with direct knowledge that verifies that the child (or children) lived with the decedent in a regular parent-child relationship at the time of the decedent's death or describing the reason(s) why the child did not live with the decedent (such as for medical reasons, to attend school, or for other similar reason) and one or more of the following proofs:
- evidence of eligibility as a dependent child for benefits under State or Federal programs;
 - cancelled checks, money orders, or receipts for periodic payments received from the decedent for or on behalf of the child;
 - evidence of goods or services that show regular contributions of considerable value by the decedent for or on behalf of the child; or
 - proof of coverage of the child as a family member under the decedent's Federal Employees Health Benefits enrollment or private health insurance.

3. *Spousal Adjustment for CATEGORY I*

For Qualified Claims awarded 55 base points under CATEGORY I, the National Settlement Administrator shall also award an additional 5 points if the decedent was married on as the date of death as evidenced by the decedent's certified death certificate.

4. *Adult Children Adjustment for CATEGORY I*

For Qualified Claims awarded 55 base points under CATEGORY I, the National Settlement Administrator shall also award an additional 3 points for each surviving natural or adopted adult child as of the date of death, up to a maximum of 9 points, provided that the Eligible Tort Trust Beneficiary lists the name, date of birth and current address of each surviving natural or adopted adult child on the National Compensation

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Claim Form and submits a copy of the decedent's obituary that identifies the surviving natural or adopted adult child(ren) or a signed statement from a person with direct knowledge that the decedent was survived by a natural or adopted adult child(ren) and identifies the surviving child(ren).

5. *Surgical Debridement or Irrigation Surgery, Laminectomy, Discectomy or Hemilaminectomy Adjustment for CATEGORIES I, II and IV*

For Qualified Claims awarded 55 base points under CATEGORY I, 40 base points under CATEGORY II, or 20 base points under CATEGORY IV, the National Settlement Administrator shall also award an additional 2 points for each separate and distinct debridement and/or irrigation surgery without a laminectomy, discectomy or hemilaminectomy, and an additional 4 points for each separate laminectomy, discectomy or hemilaminectomy whether performed contemporaneously with a debridement and/or irrigation surgery or not (if any laminectomy, discectomy or hemilaminectomy involves multiple vertebral levels, the National Settlement Administrator shall also award an additional 2 points for that surgery), after injection from one of the Three Contaminated MPA Lots, up to a maximum of 8 points, provided that the Tort Trust Beneficiary submits to the National Settlement Administrator medical records documenting each of such surgery(ies) and/or procedure(s) after injection. Medical records documenting an incision, drainage or washout shall suffice as proof of a surgical debridement or irrigation surgery. The National Settlement Administrator shall presume that all such surgical debridements and irrigation surgeries after injection from one of the Three Contaminated MPA Lots are the result of the MPA injection or complication(s) arising therefrom. The National Settlement Administrator shall presume that each laminectomy, discectomy and hemilaminectomy procedure occurring after injection and before September 30, 2013 is

6. *Anti-Fungal Complication Adjustment for CATEGORIES I, II, III, IV, V and VI*

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posaconazole, itraconazole and/or isavuconazole, or 10 points if the Tort Trust Beneficiary suffered liver injury/toxicity requiring liver transplant or placement on the waiting list for a liver transplant after treatment with voriconazole, posaconazole, itraconazole and/or isavuconazole; an additional 5 points if the Tort Trust Beneficiary suffered skin cancer after treatment with voriconazole; and an additional 3 points if the Tort Trust Beneficiary suffered periostitis after treatment with voriconazole provided that the Tort Trust Beneficiary submits medical records documenting (a) acute renal insufficiency within 30 days of the first treatment with amphotericin B, (b) acute renal insufficiency within 30 days of the first treatment with amphotericin B requiring treatment by dialysis (either temporary or permanent) within 180 days of the last treatment with amphotericin B, (c) liver injury/toxicity within 30 days of the first treatment with voriconazole, posaconazole, itraconazole and/or isavuconazole, (d) liver injury/toxicity within 30 days of the first treatment with voriconazole, posaconazole, itraconazole and/or isavuconazole requiring liver transplantation or that the Tort Trust Beneficiary was placed on the waiting list for a liver transplant within 180 days of the last treatment with voriconazole, posaconazole, itraconazole and/or isavuconazole, (e) skin cancer within 90 days of the last treatment with voriconazole as evidenced by biopsy, and/or (f) periostitis after treatment with voriconazole. Proof of acute renal insufficiency shall consist of medical records documenting a glomerular filtration rate ("GFR") of <30 within 30 days following treatment with amphotericin B. The applicable GFR score is the GFR score listed for the patient's race (non-African American or African American). If GFR scores are not available, medical records documenting a Creatinine Clearance ("CrCl") level of <30 within 30 days after the first treatment with amphotericin B is

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sufficient. Proof of liver injury/toxicity shall consist of medical records documenting a minimum of 5x upper limit of normal ("ULN") elevation in either the AST or ALT test within 30 days after the first treatment with voriconazole, posaconazole, itraconazole and/or isavuconazole.

7. *Lengthy Anti-Fungal Treatment Adjustment for CATEGORIES I, II, III, IV and V*

For Qualified Claims awarded 55 base points under CATEGORY I, 40 base points under CATEGORY II, 30 base points under CATEGORY III, 20 base points under CATEGORY IV, or 10 base points under CATEGORY V, the National Settlement Administrator shall also award an additional 2 points if, after injection from one of the Three Contaminated MPA Lots, the Tort Trust Beneficiary was treated with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole for 91 -150 days, an additional 3 points if, after injection from one of the Three Contaminated MPA Lots, the Tort Trust Beneficiary was treated with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole for 151 -210 days, an additional 4 points if, after injection from one of the Three Contaminated MPA Lots, the Tort Trust Beneficiary was treated with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole for 211 -270 days, an additional 5 points if, after injection from one of the Three Contaminated MPA Lots, the Tort Trust Beneficiary was treated with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole for 271 -330 days, an additional 6 points if, after injection from one of the Three Contaminated MPA Lots, the Tort Trust Beneficiary was treated with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole for 331-390 days, an additional 7 points if, after injection from one of the Three Contaminated MPA Lots, the Tort Trust Beneficiary was

treated with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole for 391-450 days, an additional 8 points if, after injection from one of the Three Contaminated MPA Lots, the Tort Trust Beneficiary was treated with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole for 451-510 days, an additional 9 points if, after injection from one of the Three Contaminated MPA Lots, the Tort Trust Beneficiary was treated with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole for 511-570 days, or an additional 10 points if, after injection from one of the Three Contaminated MPA Lots, the Tort Trust Beneficiary was treated with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole for more than 570 days, provided that the Tort Trust Beneficiary submits medical records documenting the length of treatment with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole after the MPA injection. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary.

8. *Lengthy Hospitalization Adjustment for CATEGORIES I, II, III, IV and V*

For Qualified Claims awarded 55 base points under CATEGORY I, 40 base points under CATEGORY II, 30 base points under CATEGORY III, 20 base points

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under CATEGORY IV, or 10 base points under CATEGORY V, the National Settlement Administrator shall also award an additional $\frac{1}{2}$ point, following 5 nights of hospitalization in an acute care hospital after injection from one of the Three Contaminated MPA Lots, for each night of inpatient stay at an acute care hospital, long-term acute care, rehabilitation, hospice or nursing home facility up to 30 nights and $\frac{1}{3}$ point for each additional night in excess of 30 nights up to a maximum of 25 points provided that the Eligible Tort Trust Beneficiary submits to the National Settlement Administrator hospital or facility records documenting at least 5 nights of inpatient hospitalization at an acute care hospital and/or records documenting the number of additional nights the decedent stayed in an inpatient acute care hospital, long-term acute care, rehabilitation, hospice or nursing home facility as a result of the MPA injection or complication(s) arising therefrom. The National Settlement Administrator shall presume that each such night of hospitalization or facility stay occurring after injection and before September 30, 2013 was the result of the MPA injection or complication(s) arising therefrom unless there is cause to believe that the hospitalization or facility stay was the result of an unrelated event (*i.e.* auto accident, unrelated illness). For hospitalizations or facility stays for which there is reason to believe are unrelated to the MPA injection or complications arising therefrom and for those occurring after September 30, 2013, proof deemed sufficient by the National Settlement Administrator that the hospitalization or facility stay was the result of the MPA injection or complication(s) arising therefrom is required. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state

only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary.

9. *Multiple Lumbar Punctures and/or CT Guided Biopsies Adjustment for CATEGORIES I, II, III, IV, V and VI*

For Qualified Claims awarded 55 base points under CATEGORY I, 40 base points under CATEGORY II, 30 base points under CATEGORY III, 20 base points under CATEGORY IV, 10 base points under CATEGORY V or 1 base point under CATEGORY VI, the National Settlement Administrator shall also award an additional $\frac{1}{2}$ point for each additional lumbar puncture and/or CT guided biopsy more than one after injection from one of the Three Contaminated MPA Lots and before September 30, 2013, up to a maximum of 4 points, provided that the Tort Trust Beneficiary submits to the National Settlement Administrator medical records documenting two or more lumbar punctures and/or CT guided biopsies after injection and before September 30, 2013. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after

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the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary.

10. *Income Adjustment for CATEGORIES I, II, III, IV and V*

For Qualified Claims awarded 55 base points under CATEGORY I, 40 base points under CATEGORY II, 30 base points under CATEGORY III, or 20 base points under CATEGORY IV, or 10 base points under CATEGORY V, the National Settlement Administrator shall also award an additional 1 point if the Tort Trust Beneficiary's 2012 or 2013 earned income was 10% to 19% less than their 2011 earned income, an additional 2 points if the Tort Trust Beneficiary's earned income was 20% to 29% less than their 2011 earned income, an additional 3 points if the Tort Trust Beneficiary's earned income was 30% to 39% less than their 2011 earned income, an additional 4 points if the Tort Trust Beneficiary's earned income was 40% to 49% less than their 2011 earned income, an additional 5 points if the Tort Trust Beneficiary's earned income was 50% to 59% less than their 2011 earned income, an additional 6 points if the Tort Trust Beneficiary's earned income was 60% to 69% less than their 2011 earned income, an additional 7 points if the Tort Trust Beneficiary's earned income was 70% to 79% less than their 2011 earned income, an additional 8 points if the Tort Trust Beneficiary's earned income was 80% to 89% less than their 2011 earned income, or an additional 9 points if the Tort Trust Beneficiary's earned income was 90% or more less than their 2011 earned income, provided that the Eligible Tort Trust Beneficiary submits to the National Settlement Administrator, the Tort Trust Beneficiary's income tax return for 2011 (whether filed jointly or single) or the Tort Trust Beneficiary's 2011 W-2(s), 1099(s) and/or 10-K(s), and the same documentation for either of the years 2012 or 2013. Earned

income shall include wages, salaries, tips, and other taxable employee pay (Form 1040, line 7), business income or loss (Form 1040, line 12), partnership or S corporation income (Form 1040, line 17), and other income (Form 1040, line 21). For CATEGORY I Qualified Claims, if the death occurred during 2012, earned income for 2013 will be deemed to be zero and no documentation of decedent's 2013 income will be required. The National Settlement Administrator shall presume that the decrease in earned income is the result of the MPA injection or complication(s) arising therefrom unless there is cause to believe that the decrease in earned income was the result of an unrelated event (*i.e.* layoff, forced work reduction, planned retirement).

11. *Stroke Adjustment for CATEGORIES II and III*

For Qualified Claims awarded 40 base points under CATEGORY II or 30 base points under CATEGORY III, the National Settlement Administrator shall also award an additional 12 points to any Tort Trust Beneficiary who suffered a cerebrovascular accident/stroke (but not a transient ischemic attack only) after injection from one of the Three Contaminated MPA Lots provided that the Tort Trust Beneficiary submits to the National Settlement Administrator medical records documenting a diagnosis of cerebrovascular accident/stroke (but not a transient ischemic attack only). If the cerebrovascular accident/stroke occurred on or before December 31, 2012, the National Settlement Administrator shall presume that the cerebrovascular accident/stroke was the result of the MPA injection or complication(s) arising therefrom unless there is a reason to believe that the cerebrovascular accident/stroke was the result of an unrelated event (*i.e.* the Tort Trust Beneficiary has a past history of cerebrovascular/accident/stroke). For cerebrovascular accidents/strokes for which there is reason to believe are unrelated to the

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MPA injection or complications arising therefrom and for those occurring after December 31, 2012, proof deemed sufficient by the National Settlement Administrator that the cerebrovascular accident/stroke was the result of the MPA injection or complication(s) therefrom is required. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary.

12. *Sacroiliac Joint Adjustment for CATEGORIES II and IV*

For Qualified Claims awarded 40 base points under CATEGORY II or 20 base points under CATEGORY IV, the National Settlement Administrator shall also award an additional 4 points if the Tort Trust Beneficiary suffered a fungal infection of a sacroiliac joint or surrounding ligaments/bones after injection from one of the Three Contaminated MPA Lots provided that the Tort Trust Beneficiary submits to the National Settlement Administrator medical records documenting the MPA injection into a sacroiliac joint or surrounding ligaments/bones and that the fungal infection occurred in a sacroiliac joint or surrounding ligaments/bones after the MPA injection. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort

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Trust Beneficiary's medical records state only that a steroid was administered on specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists). the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary.

13. *Arachnoiditis Adjustment and Neurogenic Bowel and/or Bladder Sub-Adjustment for CATEGORIES II and IV*

For Qualified Claims awarded 40 base points under CATEGORY II or 20 base points under CATEGORY IV, the National Settlement Administrator shall also award an additional 10 points if the Tort Trust Beneficiary suffered from arachnoiditis after injection from one of the Three Contaminated MPA Lots provided that the Tort Trust Beneficiary submits to the National Settlement Administrator medical records documenting (a) a diagnosis of arachnoiditis or documentation of intradural clumping, abnormal thickening or unevenness of nerve roots after MRI after injection from one of the Three Contaminated MPA Lots, and (b) documentation that the Tort Trust Beneficiary received anti-fungal treatment. In addition, for Qualified Claims that are awarded 10 points for arachnoiditis, the National Settlement Administrator shall also award an additional 2 points if the Tort Trust Beneficiary suffered from neurogenic bowel and/or neurogenic bladder dysfunction after injection from one of the Three Contaminated MPA Lots, provided that the Tort Trust Beneficiary submits to the National Settlement Administrator medical records documenting a diagnosis of neurogenic bowel and/or neurogenic bladder after September 1, 2012 and before December 31, 2013 and (a) in the case of neurogenic bowel, manifestation of symptoms

including significant constipation, fecal incontinence, fecal impaction, and/or alternating diarrhea lasting for more than 6 months, or (b) in the case of neurogenic bladder, manifestation of symptoms of urinary retention and/or urinary incontinence lasting more than 6 months and which required intermittent or regular urinary catheterization. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary.

14. *Vertebral Osteomyelitis Adjustment for CATEGORIES II and IV*

For Qualified Claims awarded 40 base points under CATEGORY II or 20 base points under CATEGORY IV, the National Settlement Administrator shall also award an additional 5 points if the Tort Trust Beneficiary suffered from vertebral osteomyelitis after injection from one of the Three Contaminated MPA Lots provided that the Tort Trust Beneficiary submits to the National Settlement Administrator medical records documenting (a) a diagnosis of vertebral osteomyelitis after injection from one of the Three Contaminated MPA Lots and (b) documentation that the Tort Trust Beneficiary received anti-fungal treatment. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical

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records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists). the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary.

15. *Peripheral Joint Infection Adjustment for CATEGORIES II, III and IV*

For Qualified Claims awarded 40 base points under CATEGORY II, 30 base points under CATEGORY III, or 20 base points under CATEGORY IV, the National Settlement Administrator shall also award an additional 3 points if the Tort Trust Beneficiary also suffered from a peripheral joint fungal infection after injection from one of the Three Contaminated MPA Lots provided the Tort Trust Beneficiary submits to the National Settlement Administrator medical records documenting (a)(i) a diagnosis of peripheral joint fungal infection (including, but not limited to, osteomyelitis and septic arthritis) after injection from one of the Three Contaminated MPA Lots into the osteoarticular structure of a peripheral joint (including the bursa and peripheral nerves) and (ii) that the Tort Trust Beneficiary received anti-fungal treatment, or (b) proof that the Tort Trust Beneficiary was listed on the a state list of NECC's peripheral joint infection cases. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists). the National Settlement Administrator shall

presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary.

16. *Hip Infection Adjustment for CATEGORY V*

For Qualified Claims awarded 10 base points under CATEGORY V, the National Settlement Administrator shall also award an additional 8 points if the Tort Trust Beneficiary's fungal infection occurred in the hip/bursa after injection from one of the Three Contaminated MPA Lots into the hip/bursa provided that the Tort Trust Beneficiary submits to the National Settlement Administrator medical records documenting that the Tort Trust Beneficiary received a MPA injection in the hip/bursa and that the fungal infection occurred in the hip/bursa after the injection. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary.

17. *Multiple Joint Fungal Infections Adjustment for CATEGORY V*

For Qualified Claims awarded 10 base points under CATEGORY V, the National Settlement Administrator shall also award an additional 4 points for each additional

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peripheral joint fungal infection after injection from one of the Three Contaminated MPA Lots into an additional peripheral joint, up to a maximum of 8 points, provided that the Tort Trust Beneficiary submits to the National Settlement Administrator medical records documenting a diagnosis of a fungal infection of an additional peripheral joint (including, but not limited to, osteomyelitis and septic arthritis) after injection into the osteoarticular structure of the additional peripheral joint (including the bursa and the peripheral nerves). If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary.

18. *Debridement/Incision Surgery Adjustment for CATEGORY V*

For Qualified Claims awarded 10 base points under CATEGORY V, the National Settlement Administrator shall also award an additional 2 points for each separate and distinct (1) debridement/incision of a joint and/or associated bursa, with or without prosthesis placement; (2) an additional 3 points for each distinct synovectomy, whether or not performed contemporaneously with a debridement and/or irrigation surgery; and /or (3) an additional 4 points for each partial or full arthroplasty with or without prosthesis placement, whether or not performed contemporaneously with a debridement

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and/or irrigation surgery or a synovectomy, after injection of one or more of the Three Contaminated MPA Lots into a peripheral joint, up to a maximum of 8 points, provided that the Tort Trust Beneficiary submits to the National Settlement Administrator medical records documenting such surgery(ies) and/or procedure(s) after injection from one of the Three Contaminated MPA Lots. Medical records documenting an irrigation, drainage or washout shall suffice for a debridement/incision surgery. The National Settlement Administrator shall presume that all debridement/incision surgeries after injection from one of the Three Contaminated MPA Lots are the result of the MPA injection or complication(s) arising therefrom. The National Settlement Administrator shall presume that each such synovectomy or arthroplasty procedure occurring after injection and before September 30, 2013 is related to the MPA injection or complication(s) arising therefrom. For synovectomies and arthroplasties occurring after September 30, 2013, proof deemed sufficient by the National Settlement Administrator that such procedure(s) was the result of the MPA injection or complication(s) arising therefrom is required. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary.

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19. *Hospitalization Adjustment for CATEGORY VI*

For Qualified Claims awarded 1 base point under CATEGORY VI, the National Settlement Administrator shall also award an additional $\frac{1}{2}$ point for each night the Tort Trust Beneficiary was hospitalized at an acute care hospital after injection of one of the Three Contaminated MPA Lots and before April 30, 2013, up to a maximum of 3 points, provided that the Tort Trust Beneficiary submits to the National Settlement Administrator hospital records documenting the number of nights hospitalized at an acute care hospital after injection and before April 30, 2013. The National Settlement Administrator shall presume that each such hospitalization was the result of the MPA injection or complication(s) arising therefrom unless there is cause to believe that the hospitalization was the result of an unrelated event (*i.e.*, auto accident, unrelated illness). For those hospitalizations for which there is reason to believe were the result of an unrelated event, proof deemed sufficient by the National Settlement Administrator that the hospitalization was the result of the MPA injection or complication(s) arising therefrom is required. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the Patient Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary.

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20. *Anti-Fungal Treatment Adjustment for CATEGORY VI*

For Qualified Claims awarded 1 base point under CATEGORY VI, the National Settlement Administrator shall also award an additional 1 point if, after injection from one of the Three Contaminated MPA Lots and before September 30, 2013, the Tort Trust Beneficiary was treated with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole for 1 - 90 days, an additional 2 points if, after injection from one of the Three Contaminated MPA Lots and before September 30, 2013, the Tort Trust Beneficiary was treated with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole for 91 - 180 days, an additional 3 points if, after injection from one of the Three Contaminated MPA Lots and before September 30, 2013, the Tort Trust Beneficiary was treated with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole for 181 - 270 days, or an additional 4 points if, after injection from one of the Three Contaminated MPA Lots and before September 30, 2013, the Tort Trust Beneficiary was treated with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole for more than 270 days, provided that the Tort Trust Beneficiary submits medical records documenting the length of treatment with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole after the MPA injection and before September 30, 2013. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the Patient Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots

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occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary.

V. Eligible Claims Involving Other Contaminated NECC Products Apart From One of the Three Contaminated MPA Lots

A. Proof of Exposure to a Contaminated Product Compounded by NECC After January 1, 2006 Apart From One of the Three Contaminated MPA Lots

In order for an Eligible Claim that does not involve an injection or injections from one of the Three Contaminated MPA Lots to be deemed a Qualified Claim, the Eligible Tort Trust Beneficiary must submit to the National Settlement Administrator medical records or other records documenting that the Tort Trust Beneficiary was administered a specified lot of NECC product that was compounded by NECC after January 1, 2006 (*i.e.*, a letter from a clinic, hospital or doctor's office informing the Tort Trust Beneficiary that he/she was administered a specified lot of NECC product). The Tort Trust Beneficiary must also submit proof deemed sufficient by the National Settlement Administrator that the administered lot of NECC product was contaminated. Examples of such satisfactory proof are the nine lots of non-MPA NECC products which have been determined by the CDC to have been contaminated (see attached Addendum A), and NECC's outside testing laboratory's determination that some lots of NECC's products were contaminated during the summer and fall of 2012 (see attached Addendum B). If the requirements listed above are satisfied, the Tort Trust Beneficiary shall be entitled to make a claim for one of the seven Base Point Categories designed for the Three Contaminated MPA Lots described in Section IV.B herein. The Tort Trust Beneficiary must satisfy the proof requirements for one of the seven Base Point Categories and adjustments applied for, except the Tort Trust Beneficiary need not provide proof of an injection from one of the Three

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Contaminated MPA Lots and references to an "injection from one of the Three Contaminated MPA Lots" in the seven Base Categories proof requirements will be read as "administration from a contaminated lot of NECC product."

B. Claims Involving an Injection or Injections of One or More of the Three Contaminated MPA Lots and Administration of a Contaminated Lot of NECC Product Apart from One of the Three Contaminated MPA Lots

In the event that a Tort Trust Beneficiary has received both an injection or injections from one or more of the Three Contaminated MPA Lots and also has been administered another contaminated NECC product, the Tort Trust Beneficiary may apply for one of the seven Base Point Categories only for either the MPA injection(s) or for the other contaminated NECC product.

VI. Eligible Claims Involving Bacterial Infection and Bacterial Meningitis

An Eligible Tort Trust Beneficiary who claims that he/she suffered from a bacterial infection or bacterial meningitis after being administered a contaminated lot of NECC product must submit to the National Settlement Administrator medical or other records documenting that the Tort Trust Beneficiary was administered a specified lot of NECC product that was compounded after January 1, 2006 (*i.e.*, a letter from a clinic, hospital, or doctor's office informing the Tort Trust Beneficiary that he/she had received a specified lot of NECC product). The Tort Trust Beneficiary must also submit to the National Settlement Administrator proof deemed sufficient by the National Settlement Administrator that the lot of NECC product administered to the Tort Trust Beneficiary was contaminated with a specific type of bacteria. Examples of such contaminated lots of NECC products are the six lots of non-MPA NECC products that have been determined by the CDC and FDA to have been contaminated with various specific types of bacteria (see Addendum A). Lot 09252012@50 of Bacitracin (stock) 50ku/20 MI solution that ARL found to be contaminated with *Paenibacillus borealis*, and Lot

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08102012@51 of MPA that was found to be contaminated with *Bacillus subtilis* and *Bacillus pumilus*. The Tort Trust Beneficiary must also submit to the National Settlement Administrator medical or other records documenting that the Tort Trust Beneficiary was infected with the same specific type of bacteria that was found to be in the contaminated lot of NECC product administered to the Tort Trust Beneficiary (*i.e.*, *Bacillus subtilis* or *Bacillus pumilus* for MPA Lot 08102012@51). If the requirements listed above are satisfied, the Tort Trust Beneficiary shall be entitled to make a claim for one of the seven Base Point Categories designed for the Three Contaminated MPA Lots. The Tort Trust Beneficiary must satisfy the proof requirements for the one of the seven Base Point Categories and adjustments applied for subject to the following:

1. *For CATEGORY I Claims:*
 - (i) the death certificate must document the immediate or underlying cause of death as "bacterial infection," "bacterial meningoenkephalitis," "bacterial encephalitis," or "bacterial meningitis," or the medical records must document a diagnosis of bacterial infection or bacterial meningitis, bacterial meningoenkephalitis or bacterial encephalitis after administration from a contaminated lot of NECC product. No medical documentation of fungal meningitis, fungal meningoenkephalitis, fungal encephalitis, or spinal or paraspinal fungal infection is required. No documentation of anti-fungal treatment is required;
 - (ii) there will be no Lengthy Anti-Fungal Treatment Adjustment or Anti-Fungal Complication Adjustment available.

2. *For CATEGORY II, III AND IV Claims:*

- (i) the medical records must document a diagnosis of bacterial meningitis, bacterial meningoencephalitis, bacterial encephalitis, or spinal or paraspinal bacterial infection after administration from a contaminated lot of NECC product. No medical documentation of fungal meningitis, fungal meningoencephalitis, fungal encephalitis, or spinal or paraspinal fungal infection is required. No documentation of anti-fungal treatment is required;
- (ii) for the Sacroiliac Joint Infection Adjustment, the medical records must document injection from a contaminated lot of NECC product into the sacroiliac joint or surrounding ligaments/bones and that the bacterial infection occurred in the sacroiliac joint or surrounding ligaments/bones after injection. No documentation of fungal infection in the sacroiliac joint is required;
- (iii) there will be no Lengthy Anti-Fungal Treatment Adjustment or Anti-Fungal Complication Adjustment available;
- (iv) for the Peripheral Joint Infection Adjustment, the medical records must document a peripheral joint bacterial infection after injection from a contaminated lot of NECC product into the peripheral joint. No documentation of a peripheral joint fungal infection is required.

3. *For CATEGORY V Claims:*

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- (i) the medical records must document a diagnosis of a peripheral joint
(e.g., hip, knee, shoulder, or ankle) bacterial infection after injection from
a contaminated lot of NECC product into the osteoarticular structure of a
peripheral joint (including the bursa and peripheral nerves). No
documentation of a peripheral joint fungal infection or of anti-fungal
treatment is required;
- (ii) for the Hip Infection Adjustment, the medical records must document a
bacterial infection in the hip/bursa after injection from a contaminated lot
of NECC product into the hip/bursa. No documentation that a fungal
injection occurred in the hip/bursa is required;
- (iii) there will be no Lengthy Anti-Fungal Treatment Adjustment or Anti-
Fungal Complication Adjustment available;
- (iv) for the Multiple Joint Fungal Infections Adjustment, the medical records
must document a bacterial infection in the additional peripheral joint after
injection from a contaminated lot of NECC product into the osteoarticular
structure of an additional peripheral joint (including the bursa and the
peripheral nerves). No documentation of a fungal infection of an
additional peripheral joint is required.

4. *For CATEGORY VI Claims:*

There will be no Anti-Fungal Treatment Adjustment or Anti-Fungal
Complication Adjustment available.

VII. Claims Assistance Program

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The National Settlement Administrator shall develop, staff and maintain a program for providing claims assistance to Tort Trust Beneficiaries ("Claims Assistance Program"). This program shall be a part of the Claims Resolution Facility, staffed by employees of the Claims Resolution Facility, and is intended to provide assistance to all Tort Trust Beneficiaries regarding the Claims Resolution Facility procedures, eligibility requirements, submission requirements (including the documentation required), denials, deficiencies, the process for curing deficiencies, obtaining re-reviews, requesting reconsideration under a different Base Point Category and appeal procedures in the event of a final denial of a claim, and the status of a Tort Trust Beneficiary's claim. The Claims Assistance Program staff shall not provide legal advice or tax advice to Tort Trust Beneficiaries.

VIII. Initial Payments On Qualified Claims

A. As soon as practicable after the Claims Deadline and after completing his/her initial review of claims, the National Settlement Administrator shall compute a tentative dollar value of each Claimed Point ("Tentative Point Value") according to the following formula: (i) calculate the sum of all Claimed Points in all of the Eligible Claims ("Summed Points"), (ii) multiply the Summed Points by a factor of 1.5 ("Enhanced Points"), and (iii) divide the National Fund Net Trust Proceeds (*i.e.*, the amount available for distribution to Tort Trust Beneficiaries at the time the computation is made) by the number of Enhanced Points:

$$[\text{Tentative Point Value} = [\text{National Fund Net Trust Proceeds} \div \text{Enhanced Points}]]$$

B. The National Settlement Administrator shall then evaluate Tort Claims in the order that they were received.

C. If an Eligible Claim is allowed in full, the Tort Trust Beneficiary's Claimed Points shall be deemed to be Approved Points, and the National Settlement Administrator shall multiply the Approved Points by the Tentative Point Value to determine the amount of the Initial

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Payment to the Claimant. The National Settlement Administrator shall notify said Tort Trust Beneficiary of the allowance of the claim in full, the amount of Approved Points, the amount of the Initial Payment, and the amount of the Initial Payment constitutes interim compensation and that the Tort Trust Beneficiary may receive additional compensation after the Claims Process is completed and all appeals from the National Settlement Administrator's final determinations have been resolved.

D. Notwithstanding anything herein to the contrary, no distribution shall be made to a Tort Trust Beneficiary if such Tort Trust Beneficiary has not returned a signed form W-9 to the National Settlement Administrator.

E. If a completed W-9 form has been received by the National Settlement Administrator, the National Settlement Administrator shall notify the Tort Trustee of the Allowed Claim and that a check should be sent to the Tort Trust Beneficiary (or, if represented by an attorney, made payable jointly to the Tort Trust Beneficiary and the attorney or law firm and sent to the attorney) in the amount of the Initial Claim Value, subject to the provisions of the Plan and the Tort Trust Agreement.

IX. Provisional Denials

A. Eligible Claims not approved in full by the National Settlement Administrator shall be deemed to be provisionally denied ("Provisional Denials"). Provisional Denials shall consist of Eligible Claims denied in whole (*e.g.*, claim did not meet the proof requirements for a Base Point Category) or denied in part (*e.g.*, an applied-for adjustment was not awarded).

B. For each Eligible Claim denied in part, the National Settlement Administrator shall sum the Points that have been approved ("Approved Points") and determine the Initial

Claim Value of the claim as approved by multiplying the Approved Points by the Tentative Point Value.

C. A "Notice of Provisional Denial" identifying the specific reason(s) for the provisional denial and, for claims denied in part, stating the number of Approved Points and the Initial Claim Value as determined in accordance with Section IX.B herein, shall be sent to the Tort Trust Beneficiary. Such notice shall also inform the Tort Trust Beneficiary of (a) the procedures and deadlines established pursuant to Section X herein for correcting deficiencies, obtaining a re-review for error, and obtaining reconsideration under a different Base Point Category, and (b) the availability of assistance through the Claims Assistance Program. Such Notices of Provisional Denial shall inform the Tort Trust Beneficiary that if the Tort Trust Beneficiary fails to follow the procedures established pursuant to Section X below within 90 days of the Notice of Provisional Denial then the Provisional Denial will be deemed to be a final determination and the Tort Trust Beneficiary will have waived any right to appeal to the Appeals Administrator and, for claims denied in part, that the Initial Claim Value will be paid after 90 days from the date of the Notice of Provisional Denial.

D. The Notice of Provisional Denial shall also inform Tort Trust Beneficiaries that the compensation payable on any Eligible Claim that is approved, in whole or in part, after being re-submitted for reconsideration under a different Base Point Category may be reduced by the National Settlement Administrator pursuant to Section XII.B herein.

X. Attempts to Cure Deficiencies, Requesting Re-review For Error or Requesting Reconsideration Under a Different Base Point Category.

A. In the event of a Provisional Denial, a Tort Trust Beneficiary shall have ninety (90) days from the date of the Notice of Provisional Denial to submit to the National Settlement Administrator (a) documentation that purports to cure some or all of the noticed deficiencies

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("attempt to cure deficiency"), (b) a request for re-review for error, which request states fully the grounds for such request ("request for re-review for error"), or (c) a request for reconsideration under a different Base Point Category, which shall be accompanied by a new National Compensation Claim Form and all required documentation in support of the new claim ("Resubmitted Claim"). A Tort Trust Beneficiary requesting reconsideration under a different Base Category shall also write or type the following at the top of the new National Compensation Claim Form: "RE-SUBMITTED CLAIM – NEW BASE POINT CATEGORY." All such documentation, requests and Resubmitted Claims must be received by the National Settlement Administrator by the Deadline imposed by this subsection.

B. The National Settlement Administrator shall evaluate and make a final determination on attempts to cure deficiencies and requests for re-reviews for error in the order in which they are received. A Notice of Final Determination shall then be sent to such Tort Trust Beneficiary, which Notice shall contain the following information (as applicable): (a) the National Settlement Administrator's final determination on the Tort Trust Beneficiary's Tort Claim, which may constitute approval in whole, approval in part, or denial in whole, and the reason(s) therefor, (b) the number of Approved Points (if any), (c) that payment of the claim (if any) will be made, subject to the provisions of the Plan and the Tort Trust Agreement, after 90 days if no appeal is sought by the Tort Trust Beneficiary pursuant to Section XI herein, (d) in the event of a denial in whole or in part, notice of the appeals procedure available pursuant to Section XI herein; and (e) the availability of assistance through the Claims Assistance Program.

C. In order to encourage the accuracy of originally-filed Tort Claims, to reduce the administrative costs to the Tort Trust of re-considering claims under different Base Point Categories, and to be able to make Initial Payments to Tort Trust Beneficiaries, the National

Settlement Administrator shall hold for review all requests for reconsideration under a different Base Point Category until all other claims (including those involving attempts to cure deficiencies and requests for re-review for error pursuant to Section X.B herein, but not claims that are appealed to the Appeals Administrator) have been finally determined. The National Settlement Administrator shall thereafter review and make a final determination on all requests for reconsideration under a different Base Point Category in the order that they were received. A Notice of Final Determination shall then be sent to such Tort Trust Beneficiaries, which notice shall contain the following information: (a) the National Settlement Administrator's final determination on the Tort Trust Beneficiary's claim, which may constitute approval in whole, approval in part, or denial in whole, and the reason(s) therefore; (b) the number of Approved Points (if any); (c) in the event of a denial in whole or in part, notice of the appeals procedure available pursuant to Section XI herein; (d) notice that any awards on requests for reconsideration under a different base point category, whether allowed in whole or in part, may be reduced pursuant to Section XII.B herein and will not be paid until the Final Payments to Tort Trust Beneficiaries have been calculated; and (e) the availability of the Claims Assistance Program.

D. In the event that a Tort Trust Beneficiary does not submit to the National Settlement Administrator, pursuant to Section X.A., herein, within ninety (90) days from the date of the Notice of Provisional Denial, an attempt to cure a deficiency, a request for re-review for error or a request for reconsideration under a different Base Point Category, the National Settlement Administrator's Provisional Denial shall automatically become a final determination and the Tort Trust Beneficiary shall have waived any right to exercise the appeal procedures set out in Section XI herein. If any such provisional denial that automatically becomes a final

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determination included an award of Approved Points and an Initial Claim Value, the National Settlement Administrator shall notify the Tort Trustee of the Approved Claim and that a check should be sent to the Tort Trust Beneficiary (or, if represented by an attorney, a check made payable jointly to the Tort Trust Beneficiary and the attorney or law firm and sent to the attorney) in the amount of the Initial Claim Value for said claim subject to the provisions of the Plan and the Tort Trust Agreement.

XI. Appeals From Final Determinations

A. Any Tort Trust Beneficiary aggrieved by a final determination made by the National Settlement Administrator who has not waived the right of appeal pursuant to the provisions of Section X.D herein shall have the right to appeal such final determination to the Appeals Administrator. To be eligible for consideration by the Appeals Administrator, any such appeal must be in the form of a written statement explaining the Tort Trust Beneficiary's contentions and must be received by the Appeals Administrator on or before thirty (30) days after the date of the National Settlement Administrator's final determination. The Appeals Administrator shall notify the National Settlement Administrator of any such appeal and the National Settlement Administrator shall promptly forward to the Appeals Administrator a copy of the Tort Trust Beneficiary's claim file for each appeal.

B. For claims denied in full, the Appeals Administrator shall (1) perform a *de novo* evaluation of the denial in full in accordance with the applicable provisions of Sections III-VI herein, (2) if no upward adjustments to a Base Point Category were claimed, make a final determination as to whether the claim should be allowed and the number of Approved Points allowed for each such claim, which may be reduced by the National Settlement Administrator in accordance with Section XII.B herein for any claim that was approved after reconsideration

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under a different Base Point Category, (3) if upward adjustments to a Base Point Category were claimed, make a final determination as to whether the claim should be allowed under the Base Point Category claimed, and, if such claim is so allowed, remand the matter to the Settlement Administrator to allow him or her to issue a provisional determination on the upward adjustments claimed, and (4) inform the respective Tort Trust Beneficiary and the National Settlement Administrator in writing of the action taken by the Appeals Administrator and the number of Approved Points, if any.

C. For claims denied in part, the Appeals Administrator shall (1) perform a *de novo* evaluation of the partial denial in accordance with the applicable provisions of Sections III-VI herein, (2) make a final determination of the number of Approved Points allowed for each such claim, which may be reduced by the National Settlement Administrator in accordance with Section XII.B herein for any claim that was approved after reconsideration under a Different Base Category, and (3) inform the respective Tort Trust Beneficiaries and the National Settlement Administrator in writing of such final determination and the number of Approved Points. The Appeals Administrator's final determination shall be final and binding.

XII. Final Payments to Tort Trust Beneficiaries

A. Within 120 days after all claims are finally determined, all appeals are resolved by the Appeals Administrator, and the final resolution of any appeals of the Bankruptcy Court's Confirmation Order, the National Settlement Administrator shall compute the final dollar value of each Approved Point ("Final Point Value") by dividing the Net Distribution Amount (*i.e.*, the total amount previously paid to Tort Trust Beneficiaries and the amount available to be paid in compensation to Tort Trust Beneficiaries) by the sum of (i) all Approved Points for claims approved in full pursuant to Section VIII.C herein, (ii) all Approved Points for claims finally

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determined by the National Settlement Administrator pursuant to Section X.A-D herein, including those claims that were re-submitted for review under a different Base Point Category and (iii) all Approved Points for claims finally determined by the Appeals Administrator pursuant to Section XI herein.

B. In the event that the computation in Section XII.A herein yields a final dollar value of each Approved Point that is less than the Tentative Point Value, then the National Settlement Administrator shall reduce, on a *pro rata* basis, the Approved Points awarded on claims that were re-submitted for review under a different Base Point Category in such amount as is required for the computation in Section XII.A herein to yield a final dollar value of each Approved Point that is equal to the Tentative Point Value. Such final dollar shall be considered the Final Point Value.

C. In the event that the computation in Section XII.A herein yields a final dollar value of each Approved Point that is greater than the Tentative Point Value, then such final dollar value of each Approved Point shall be considered the Final Point Value.

D. The National Settlement Administrator shall then determine the final compensation amount for each Qualified Claim ("Final Compensation Amount") by multiplying the Approved Points times the Final Point Value on each Qualified Claim.

E. Promptly thereafter, the National Settlement Administrator shall notify the Tort Trustee to make the following disbursements:

1. If the Final Point Value exceeds the Tentative Point Value, then each Tort Trust Beneficiary who received an Initial Payment pursuant to Section VIII.C or X.D above shall be paid (or, if represented by an attorney, paid jointly with the attorney or law firm) an additional amount equivalent to the difference between the Tort Trust

Beneficiary's Final Compensation Amount and the Initial Payment, subject to the provisions of the Plan and the Tort Trust Agreement.

2. All other Tort Trust Beneficiaries whose Tort Claim has been approved in whole or in part shall be paid (or if represented by an attorney, paid jointly with the attorney or law firm) an amount equivalent to the Tort Trust Beneficiary's Final Compensation Amount subject to the provisions of the Plan and the Tort Trust Agreement.

F. Additional Assets Received by the Tort Trust after the Final Payments have been made to the Tort Trust Beneficiaries may be disbursed on a pro rata basis to Tort Trust Beneficiaries or otherwise, pursuant to the provisions of the Plan and the Tort Trust Agreement.

XIII. Prevention and Detection of Fraud

A. The National Settlement Administrator may institute claim auditing procedures and other procedures to detect and prevent the allowance of fraudulent claims. All claims must be signed under the pains and penalties of perjury. The submission of a fraudulent claim will violate the criminal laws of the United States, including the criminal provisions applicable to Bankruptcy Crimes, 18 U.S.C. § 152, and subject those responsible to criminal prosecution in the federal courts. If the National Settlement Administrator determines that a claim is fraudulent, the National Settlement Administrator shall deny the claim and so inform the Tort Trust Beneficiary and the Tort Trustee.

B. The National Settlement Administrator shall have the authority to request the Tort Trust Beneficiary to submit additional medical, hospital, facility or other records in order to make a determination of allowance or denial of any claim. If the Tort Trust Beneficiary refuses to or fails to respond to such a request within ninety (90) days or if the National Settlement

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Administrator determines that a Tort Trust Beneficiary's response is inadequate, the National Settlement Administrator shall take such actions as he or she deems appropriate on the claim and notify the Tort Trust Beneficiary of the action and basis therefore.

C. The National Settlement Administrator may conduct random audits to verify supporting documentation submitted (including death certificates, medical and other records) by randomly selecting claims and may audit individual claims or groups of claims.

D. All Tort Trust Beneficiaries must certify to the National Settlement Administrator on the National Compensation Claim Form that the Tort Trust Beneficiary has not transferred his or her right to recover from the Released Parties with respect to his or her Claim such that the Claim can be asserted by another person or entity. The fact that a Tort Trust Beneficiary has executed a "subrogation" agreement with a health insurer or that a statutory provision grants to any governmental entity rights of subrogation shall not of itself be construed as a transfer of the Tort Trust Beneficiary's right to recover.

XIV. Closure of the Claims Resolution Facility

Within ninety (90) days after all Qualified Claims have been paid by the Tort Trust, the National Settlement Administrator shall wind up the affairs of the Claims Resolution Facility and the National Settlement Administrator and the Tort Trustee shall file a joint final report with the Bankruptcy Court and the District Court. The final report shall specify the total number of Claims filed in each of the seven Base Point Categories, the Tentative Point Value of each point, the Final Point Value of each point, the total number of Qualified Claims in each Base Point Category, the total number of points awarded in each Base Point Category, and the total amounts paid to each Tort Trust Beneficiary in each Base Point Category.

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XV. Notices to the National Settlement Administrator

To be effective, all requests, notices, Claims, and Resubmitted Claims to or upon the National Settlement Administrator and/or the Claims Resolution Facility shall be in writing, and unless otherwise expressly provided herein, shall be deemed to have been duly given or made when actually delivered to the National Settlement Administrator at the address set forth below:

XVI. Notices to the Appeals Administrator

To be effective, an appeal made to the Appeals Administrator shall be in writing and, unless otherwise expressly provided herein, shall be deemed to have been duly given or made when actually delivered to the Appeals Administrator at the address set forth below:

Home Drugs Drug Safety and Availability Multistate outbreak of fungal meningitis and other infections

Multistate outbreak of fungal meningitis and other infections



Laboratory Testing and Results

[12-17-2012] FDA and CDC have identified bacterial and/or fungal contamination in unopened vials of betamethasone, corticosteroids, and triamcinolone solutions distributed and recalled from NECC. These include bacteria known as *Bacillus*, and fungal species including *Aspergillus tubingensis*, *Aspergillus fumigatus*, *Cladosporium* species, and *Penicillium* species. Although rare, some of the identified *Bacillus* species can be human pathogens. Some of the fungal organisms identified, particularly *Aspergillus fumigatus*, are known to cause disease in humans. It is not known how product contamination with these organisms could affect patients clinically. See CDC's Advice for Clinicians.

CDC and FDA Laboratory-Confirmed Organisms from Product Samples
Laboratory-Confirmed Organisms from Product Samples Associated with
NECC Recalled Lots of Betamethasone, Corticosteroids, and Triamcinolone Solutions

Medication	Lot Number	Bacteria and Fungal Contamination
Betamethasone 6 mg/mL injectable - 5 mL per vial	08202012@141	<i>Paenibacillus pabuli/amolyticus</i> , <i>Bacillus idiensis</i> , <i>Bacillus flexus</i> , <i>Bacillus simplex</i> , <i>Lysinibacillus</i> sp., <i>Bacillus niacini</i> , <i>Kocuria rosea</i> , <i>Bacillus lentus</i>
Betamethasone 6 mg/mL injectable - 5 mL per vial	07032012@22	<i>Bacillus niabensis</i> , <i>Bacillus circulans</i>
Betamethasone 12 mg/mL injectable - 5 mL per vial	07302012@52	<i>Bacillus lentus</i> , <i>Bacillus circulans</i> , <i>Bacillus niabensis</i> , <i>Paenibacillus barenholtzii/timonensis</i>
Betamethasone 6 mg/mL injectable - 5 mL per vial	08202012@44	<i>Bacillus lentus</i> , <i>Bacillus firmus</i> , <i>Bacillus pumilus</i>
Betamethasone 6 mg/mL injectable - 5 mL per vial	08152012@84	<i>Penicillium</i> sp., <i>Cladosporium</i> sp.
Triamcinolone 40 mg/mL injectable - 1 mL per vial	06062012@6	<i>Bacillus lentus</i> , <i>Bacillus circulans</i> , <i>Bacillus niabensis</i> , <i>Bacillus nealsonii</i> , <i>Bacillus subtilis</i> group, <i>Bacillus firmus</i>
Triamcinolone 40 mg/mL injectable - 2 mL per vial	08172012@60	<i>Aspergillus tubingensis</i> , <i>Penicillium</i> sp.
Triamcinolone 40 mg/mL injectable - 10 mL per vial	08242012@2	<i>Aspergillus fumigatus</i>
Corticosteroids solution 265.5 mL per bag	09242012@55	<i>Bacillus halmapilus/norikoshii</i> , <i>Brevibacillus choshinensis</i>

Related Information

- FDA Form 483 for New England Compounding Center (PDF - 1.7 MB)¹
- Archive of Updates on Fungal Meningitis Outbreak²
- List of Recalled Products Related to Fungal Meningitis Outbreak⁴
- Meningitis Outbreak: Voriconazole and Liposomal Amphotericin B Availability Information⁵

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- 4 [/Drugs/DrugSafety/ucm322752.htm](#)
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Addendum B

**ARL LABORATORY
CONFIRMED CONTAMINATION FROM NECC NON-MPA PRODUCT SAMPLES**

Medication	Lot Number
Bacitracin 50,000 units in 20ml 0.9% Sodium Chloride	07232012@125
Polym-Bari (STOCK) 3L *Glen Falls* 1.5mu-30KU/30mL solution	08062012@115
Polymyxin/Bacitracin *Winchester* 1mu-50KU/20mL solution	08272012@87
Sodium Bicarbonate 150mEq/1000ml in Sterile Water for injection	08282012@110
Bacitracin (STOCK) 50KU/20mL solution	09252012@90
Potassium Chloride Sterile Solution Concentrate, USP 2mEq/ml (500mEq)	09252012@94